Cannabis Returns to United States Pharmacopeia

ANALYTICAL
Starting a QC Testing Lab: What You Need to Know About ROI, Testing Requirements, and More

CULTIVATION
Arno Hazekamp Discusses the Legal Cannabis Coalition, Research, Education, and More

EXTRACTION
Hazardous Location Requirements for Chemical Process Areas

RESEARCH
CANN Virtual Symposium Meeting Report

MANUFACTURING/PROCESSING
How to Get Started with GxP Compliances

INDUSTRY TRENDS
Chemist’s Guide to COVID-19

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<td>Class F1 Weights 1mg-1kg</td>
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SUBSCRIPTIONS: For subscription and circulation information: Cannabis Science and Technology, PO Box 457, Cranbury, NJ 08512-0457, or email mmhinfo@mmhgroup.com. Delivery of Cannabis Science and Technology outside the United States is 14 days after printing.

CHANGE OF ADDRESS: Send change of address to Cannabis Science and Technology, PO Box 457, Cranbury, NJ 08512-0457; alternately, send change via email to fullfill@mmhassoc.com or go to the following URL: http://mmhpubs.mmhgroup.com/Welcome.aspx?pubid=CNST. Allow four to six weeks for change.

Cannabis science and technology (Print ISSN: 2643-8844, Digital ISSN: 2643-8852) is published Bi-Monthly 6 times/year by MultiMedia Healthcare LLC, 2 Clarke Drive, Suite 100, Cranbury, NJ 08512.

POSTMASTER: Please send address changes to CANNABIS science and technology, PO Box 457, Cranbury, NJ 08512-0457. Return Undeliverable Canadian Addresses to: IMEX Global Solutions, P. O. Box 25542, London, ON N6C 6B2, CANADA. Canadian G.S.T. number: R-124213133RT001. Printed in the U.S.A.

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Contents

CANNABIS SCIENCE AND TECHNOLOGY | VOL 3 • NO 5 www.CannabisScienceTech.com

CANNABIS ANALYSIS

10 Hope on the Hemp Testing Horizon
Brian C. Smith
A proper set of hemp standard reference materials courtesy of the University of Kentucky are now available and the implications of this for hemp testing are discussed.

EXTRACTION SCIENCE

14 Hazardous Location Requirements for Chemical Process Areas in Extraction Facilities
Rob James
This article explores hazardous location requirements and hazardous area classification as they relate to extraction facility design and construction, specifically diving into the National Fire Protection Association code 497.

NAVIGATING THE LABYRINTH: CHALLENGES IN THE CANNABIS LABORATORY

17 Everything Old is New Again: Cannabis Returns to USP
Patricia L. Atkins
Here we examine the history of cannabis in the US, the role the USP played in that field, and the new role the USP is taking with cannabis for medical use.

CANNABIS CROSSROADS

23 A Tribute to the Life and Legacy of Charlotte Figi
Joshua Crossney
A tribute piece to Charlotte Figi, a medical cannabis and CBD pioneer who inspired the name of the medical cannabis strain Charlotte’s Web.

FEATURES

25 Starting a QC Cannabis or Hemp Laboratory: Testing Requirements, Initial Expenses, and ROI
Bob Clifford
How quickly can a cannabis or hemp testing laboratory see return on investment?

32 Getting Started with GxP Compliance in Your Cannabis Laboratories and Facilities
Benoît Chedhomme
In this article, you will learn about the GxP requirements for laboratories, production facilities, and distribution of cannabis.

36 Spring 2020 CANN Virtual Symposium Meeting Report
Madeline Colli
A report on the two-day Cannabis Chemistry Subdivision’s Spring 2020 Virtual Symposium that took place in early May.

39 A Chemist’s Guide to the COVID-19 Outbreak
Patricia Atkins and Rebekah Biermann
This informational article is an attempt to organize all of the pertinent information about COVID-19 and pandemics from a chemistry point of view.

46 The Legal Cannabis Coalition: A Closer Look at How Dutch Horticultural Companies and Scientific Partners Joined Forces
Megan L’Heureux
Dr. Arno Hazekamp discusses the formation of the new coalition as well as their goals, research, and education initiatives.

DEPARTMENTS

07 Editorial Advisory Board
08 Cannabis News Focus
09 Application Note
Cannabis Science and Technology’s Editorial Advisory Board is a group of distinguished individuals assembled to help the publication fulfill its editorial mission to educate the legal cannabis industry about the science and technology of analytical testing and quality control. With recognized expertise in a wide range of areas, board members perform various functions, such as suggesting authors and topics for coverage, reviewing manuscripts, and providing the editor with general direction and feedback. We are indebted to these individuals for their contributions to the publication and to the cannabis community as a whole.
Cannabis Industry Continues to Provide Aid to Communities in Need Amid COVID-19 Pandemic

Personal protective equipment (PPE) has been a difficult item to track down during the COVID-19 global pandemic. Extract Consultants, a provider of terpenes, flavors, and effects blends that are specifically designed for the tetrahydrocannabinol (THC) and hemp industries, recently saw the need and urgency for PPE materials in their Denver communities.

In May, Extract Consultants published a press release informing the public that they had donated 700 KN95 masks to Denver Health’s Ernest E. Moore Shock Trauma Center, which is reportedly one of the highest volume trauma centers in the nation, managing trauma cases from Colorado and six neighboring states. Extract Consultants said they were honored to donate masks to this facility in their press release (1).

“Treating COVID-19 patients while safely providing ongoing medical care for other conditions requires Denver Health to think creatively, act fast and take extraordinary measures at great but necessary expense,” said Linda Ford, Denver Health Executive Director (2). “Extract Consultants’ generous contribution of face masks makes that a reality.”

Their thoughtful gesture did not end with PPE donations. With the COVID-19 pandemic, many are out of work and unable to provide for their families. Extract Consultants provided a financial contribution to the Food Bank of the Rockies, which will contribute to approximately 12,000 meals to its Denver communities facing food insecurities (2). The Food Bank of the Rockies is the largest private hunger-relief organization in Colorado and Wyoming.

“This crisis has brought to bear the ever-present need for goodwill and generosity in our local community,” said Extract Consultants President Maxwell Brown (2). “We’re grateful to be able to support these vital organizations serving the most vulnerable here in Denver.”

From Extract Consultant’s press release, the company commented further on the amount of donations and other assistance being performed by other cannabis establishments (1): “We continue to be awed by the incredible acts of compassion and generosity shown by those within and without our industry. We are all truly in this together.” Businesses in the cannabis industry continue to pursue ways on how to aid each other and their communities to get through these difficult times (3).

References

Perry Johnson Registrars Food Safety, Inc. Granted Accreditation for Cannabis Certification Standard

Perry Johnson Registrars Food Safety, Inc. (PJRFSI) recently announced in a press release that they have become the first certification body to be granted accreditation in the United States for cannabis certification by the ANSI National Accreditation Board (ANAB) (1).

The cannabis certification standard developed by PJRFSI are good manufacturing practice (GMP) and good agricultural practice (GAP) schemes that aim to assist those working in the cannabis industry—namely, cannabis growers, manufacturers, and retailers. The certification standards will help cannabis companies meet state-by-state requirements.

The PJRFSI standard is intended to supply outlines for cannabis cultivation, retail practices nationwide, and product manufacture. In the press release (1), PJRFSI noted what they hoped to achieve with their history-making certification: “With the release and accreditation of their standard, PJRFSI hopes to simplify and unite the United States cannabis industry for the benefit of everyone from grower to producer to end user.”

“The team at Perry Johnson Registrars Food Safety Inc. is incredibly excited to be the first company in the United States to achieve formal accreditation for our Cannabis and Hemp Certification Program,” said PJRFSI President Terry Boboige and Accreditation Manager Lauren Maloney in the press release (1). “We believe this nationally-recognized program will help the budding cannabis and hemp industries to strengthen, legitimize, and separate themselves from companies that do not have formal certification.”

References
   — Madeline Colli
In humans, cytochrome P450 contains three primary enzymes involved in the metabolism of Δ9-tetrahydrocannabinol (CYP2C9, CYP2C19, CYP3A4). These enzymes are mostly found in the liver, but can occur in other lipophilic tissues like brain, small intestine, heart, and lungs. THC elimination in the body is dictated by the accumulation of the compound in both adipose tissue and plasma and, due to the lipophilicity of THC, the determination of the concentration through excretion is difficult. Likewise, states have passed regulations allowing for the legal use of both medicinal and recreational cannabis while workplaces in those states continue to dictate safety regulations with a zero tolerance drug policy culminating in a urine test to determine compliance. With more than 100 THC metabolites, detection of the most abundant, 11-hydroxy-THC, 11-carboxy-THC glucuronide, and 11-carboxy-THC, hold the most focus. Typically, between 80% and 90% of the THC consumed is excreted as carboxylate and hydroxylate metabolites.

The Hamilton PRP-C18 reversed-phase column offers good selectivity and peak shape when detecting the three major components of THC metabolites in urine. As shown in Figure 2, samples spiked with metabolites in urine show good correlation in low concentrations and rapid sample analysis can be achieved in under eight minutes. In addition to good column performance, all Hamilton columns come with value added features that include great chemical and thermodynamic stability and increased lifetime due to their PS-DVB backbone.

Figure 2: Urine sample spiked with 3 ng/mL of THC metabolites.

Figure 1: Most abundant THC metabolites.

Column Information

Packaging Material
PRP-C18, 5 µm

P/N
79676

Chromatographic Conditions

Gradient
0.00–2.00 min, 5%B
2.01–3 min, 5–50%B
3.01–8 min, 50–95%B
8.01–10 min, 95%B

Temperature
35°C

Injection Volume
5 µL

Detection
UV at 230 nm

Dimensions
150 x 4.6 mm

Eluent A
10 mM CH3COONH4

Eluent B
CH3CN

Flow Rate
2.0 mL/min

Literature


Author: Adam L. Moore, PhD
Hope on the Hemp Testing Horizon

The lack of cannabis standard reference materials means the phenomenon of inter-laboratory error is still with us. This problem is so bad it means results from different laboratories should not be compared to each other. The good news is that their finally exists a proper set of hemp standard reference materials courtesy of the University of Kentucky. The implications of this for hemp testing are discussed.

Brian C. Smith

The inter-laboratory error problem strikes again. Myself and others have researched and written extensively on that problem in the cannabis analysis industry (1–7). This problem occurs when different laboratories obtain markedly different results on the same samples. Unfortunately, the problem is still with us as seen in Tables I and II, which show the total tetrahydrocannabinol (THC) and total cannabidiol (CBD) measurements on a set of three hemp samples sent to two different laboratories.

Both laboratories S and N are fully state licensed, International Organization for Standardization (ISO) certified, and enjoy a good reputation in the cannabis industry. If we had the right level of standardization, these two laboratories would obtain the same results on the same samples within their margin of error (8). The results in Tables I and II clearly show this is not the case. The standard deviation for total THC between the two laboratories is 0.11 wt.%. This may seem small and acceptable. However, legal hemp cannot contain more than 0.3% total THC by dry weight (9,10), and the inter-laboratory error (standard deviation) of 0.11%, when divided into 0.3%, represents a relative error of 36.6%. This is way too large to be thought accurate. The inter-laboratory error is particularly acute for the sample C4 listed in Table I. Laboratory S found 0.33% total THC, while Laboratory N found 0.21% total THC. The difference of 0.12% means Laboratory S says the material is illegal, whereas Laboratory N says it is legal. Thus, the choice of laboratory determines whether a hemp farmer can sell their crop or not. Who are we to believe here?

The situation for total CBD measurements is worse, as seen in Table II. This value is used to determine hemp prices. The standard deviation between the two laboratories is 2.1 wt.% total CBD. This much of a difference can cost hemp farmers thousands of dollars when they go to sell their crop. Again, the choice of laboratories determines the success or failure of the hemp farmer. Who are we to believe? The livelihood of thousands of farmers, and millions of dollars, are at stake each harvest season, and depend upon the accuracy of these measurements. The ongoing problem of inter-laboratory error means that our cannabis testing regulatory framework is inadequate and needs to be fixed (6).

The Search for Cannabis Standard Reference Materials

One of the causes of inter-laboratory error is the lack of cannabis standard reference materials (SRMs) (5). This would be a set of samples whose composition the stakeholders in this industry can agree upon. These samples could then be used in round-robin studies to compare laboratories, ascertain method quality, and research new testing technologies.

In the United States the National Institutes of Standards and Technology (NIST) is the Federal agency tasked with generating SRMs...
Cannabis Analysis

The lack of SRMs affects our ability to calculate accuracies in cannabis analysis. But first, we need to clarify how “accuracy” should be calculated for chromatographic cannabis potency measurements. Typically, chromatographs are calibrated for potency using solutions of cannabinoids of known concentration (14–16). This is appropriate because due to the sample preparation required for chromatography, the sample being injected into the chromatograph is a solution of cannabinoids. In this case, the true value comes from the known amounts of cannabinoids in the pure standards, and an accuracy calculation is possible. Impressive potency measurement accuracies are possible when analyzing pure cannabinoids (14–16).

The lack of appropriate SRMs makes it impossible to calculate a true accuracy value for real cannabis samples. This is why I say the concept of accuracy is a myth in cannabis analysis. This, combined with variations in method across laboratories, is why you can’t compare numbers across laboratories. The inter-laboratory error, documented for example in Tables I and II, is too large.

At the end of the day the problem isn’t that one laboratory’s method is “right” and some other laboratory’s method is “wrong.” The problem is that the lack of SRMs and standardization means that no two laboratories use the same exact methods, which means no two laboratories are going to get the exact same result on the same samples.

This does not mean precision measurements cannot be made. Recall that precision is a measure of reproducibility (8). A laboratory could determine its method’s precision by analyzing multiple aliquots of the same sample and then comparing the results. This measurement, and not how well a method analyzes pure standards, is for now the best measure we have of cannabis analysis method quality.

Table I: Comparison of total THC values between two laboratories for a set of hemp samples

<table>
<thead>
<tr>
<th>Sample</th>
<th>Lab S</th>
<th>Lab N</th>
<th>Difference</th>
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<td>C4</td>
<td>0.33</td>
<td>0.21</td>
<td>0.12</td>
</tr>
<tr>
<td>Mountain Mango</td>
<td>0.14</td>
<td>0.22</td>
<td>-0.08</td>
</tr>
<tr>
<td>Frosted Lime</td>
<td>0.5</td>
<td>0.42</td>
<td>0.08</td>
</tr>
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</table>

Bias = 0.04
Std. Dev. = 0.11

Table II: Comparison of total CBD values between two laboratories for a set of hemp samples

<table>
<thead>
<tr>
<th>Sample</th>
<th>Lab S</th>
<th>Lab N</th>
<th>Difference</th>
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<tr>
<td>C4</td>
<td>8.42</td>
<td>7.25</td>
<td>1.17</td>
</tr>
<tr>
<td>Mountain Mango</td>
<td>4.73</td>
<td>7.54</td>
<td>-2.81</td>
</tr>
<tr>
<td>Frosted Lime</td>
<td>13.1</td>
<td>12.74</td>
<td>0.36</td>
</tr>
</tbody>
</table>

Bias = -0.43
Std. Dev. = 2.1

Hope on the Hemp Testing Horizon

The search for a set of SRMs for hemp is over. The University of Kentucky (UKY) has developed a set of hemp standard reference materials as part of their Hemp Proficiency Program (HPP) (17). This sample set consists of four legal hemp samples, each of which has been analyzed by dozens of cannabis analysis laboratories across the country. The certificates of analysis that come with these samples contain the average total THC, total CBD, and other cannabinoid weight percents as determined by these laboratories.

I have vetted these SRMs by sending three aliquots of each sample for high performance liquid chromatography (HPLC) analysis to a laboratory I trust, SC Labs of Santa Cruz,
Califronia (18). The purpose was to assess the homogeneity of the samples. The results for total THC are seen in Table III.

The difference between triplicate analyses of the same sample are in the third decimal place. This indicates the UKY hemp samples are homogeneous. This is impressive considering how inhomogeneous hemp plant material is, and how hard it is to render these samples uniform.

My other way of assessing the quality of the UKY samples was to see how well their values compared with those of SC Labs. The results for total THC are seen in Table IV.

Note that the differences are on the order of 0.03 wt.%. This excellent agreement convinces me that the weight percent cannabinoid values on the certificates of analysis that come with the UKY samples are correct.

This means we finally have an independent set of hemp SRMs—a set of hemp plant material samples with true cannabinoid content values. This sample set allows true accuracy calculations to be made, individual laboratories can evaluate their methods by comparing themselves to true standards, inter-laboratory round-robin studies can be performed to evaluate different methods, and a sample set exists with which to compare results from new testing technologies (19).

I strongly encourage all cannabis testing laboratories in the US interested in testing hemp to analyze this sample set, and participate in the University of Kentucky’s Hemp Proficiency Program (17).

**Conclusions**

The problem of inter-laboratory error continues to plague the cannabis analysis industry. This makes it difficult, for example, to set the purchase price for cannabis materials. A part of the problem is the lack of cannabis standard reference materials. Fortunately, the University of Kentucky has developed a set of hemp validation samples as part of their Hemp Proficiency Program. I have vetted these samples and am convinced they are legitimate. The hemp testing industry should be using these samples in round robin studies to ascertain method and laboratory quality, and develop new and better cannabis analysis methods.

**References**


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**Table III:** Total THC weight percent results for triplicate analysis of UKY hemp standard reference materials set as measured by HPLC

<table>
<thead>
<tr>
<th>Sample</th>
<th>Aliquot 1</th>
<th>Aliquot 2</th>
<th>Aliquot 3</th>
<th>Average</th>
<th>Std. Dev.</th>
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<tr>
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<td>0.25</td>
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<td>0.26</td>
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<td>HM19NOV-1</td>
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<td>0.006</td>
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**Table IV:** Comparison of total THC weight percent values for UKY hemp standard reference materials set as measured by HPLC

<table>
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<th>Sample</th>
<th>KY Value</th>
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<th>Difference</th>
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<tr>
<td>HM19SEP-1</td>
<td>0.29</td>
<td>0.26</td>
<td>0.03</td>
</tr>
<tr>
<td>HM19SEP-2</td>
<td>0.14</td>
<td>0.11</td>
<td>0.03</td>
</tr>
<tr>
<td>HM19NOV-1</td>
<td>0.3</td>
<td>0.28</td>
<td>0.02</td>
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<td>HM19NOV-2</td>
<td>0.07</td>
<td>0.04</td>
<td>0.03</td>
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<tr>
<td>Bias =</td>
<td></td>
<td>0.0275</td>
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</tr>
<tr>
<td>ASEP =</td>
<td></td>
<td>0.005</td>
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</table>


17) http://www.rs.uky.edu/regulatory/hpt/.


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**About the Columnist**

Brian C. Smith, PhD, is Founder, CEO, and Chief Technical Officer of Big Sur Scientific. He is the inventor of the BSS series of patented mid-infrared based cannabis analyzers. Dr. Smith has done pioneering research and published numerous peer-reviewed papers on the application of mid-infrared spectroscopy to cannabis analysis, and sits on the editorial board of *Cannabis Science and Technology*. He has worked as a lab director for a cannabis extractor, as an analytical chemist for Waters Associates and PerkinElmer, and as an analytical instrument salesperson. He has more than 30 years of experience in chemical analysis and has written three books on the subject. Dr. Smith earned his PhD on physical chemistry from Dartmouth College.
Hazardous Location Requirements for Chemical Process Areas in Extraction Facilities

Cannabis or hemp extraction typically involves the use of hazardous materials, including flammable liquids, gases, or vapors. The use and storage of these hazardous materials, coupled with the complex electrical systems and equipment utilized in extraction facilities, leads to a myriad of safety hazards that business owners must be aware of. This article explores hazardous location requirements and hazardous area classification as they relate to extraction facility design and construction, specifically diving into the National Fire Protection Association (NFPA) code 497. Some of the topics we discuss in this article include: equipment and safety standards required to be implemented in hazardous areas and important considerations when making these decisions; how to ensure compliance with local jurisdictions and other governing bodies; building the right team of experts to ask the right questions and avoid common pitfalls; important equipment and space considerations to keep top of mind before purchasing any equipment; and hazardous area classifications and what that means for your facility.

Rob James

Hemp and cannabis extraction facilities typically use a variety of hazardous materials in the extraction and refinement processes. These materials can include ethanol, methanol, propane, butane, hexane, heptane, and pentane—among others. Carbon dioxide may also be used, and although it isn’t flammable or explosive, it is an asphyxiant, which can cause suffocation to occupants and therefore comes with its own life-safety considerations. When it comes to hazardous materials, it is important to understand the quantity of each material used and stored in your facility. It is these quantities that will determine the type of construction required for your facility and can dramatically affect construction costs.

Control Areas and Maximum Allowable Quantities

Many facilities can avoid a hazardous classification if they can limit the use and storage of hazardous materials to specified control areas (or rooms). A control area is a term used in the building codes and is defined as a portion of a building within which hazardous materials are allowed to be stored, dispensed, used, or handled in quantities not exceeding the maximum allowed quantities (MAQ). The number of control areas is limited by the building codes, and is determined by the quantities and types of hazardous materials used and stored within your facility. If your process requirements can stay within the MAQ, the building may not need to be classified as a hazardous occupancy (that is, H occupancy), which may avoid the higher construction costs associated with a hazardous occupancy building classification. Instead, specified control areas within the building will be designed as hazardous classification areas where any hazardous materials are used or stored. For example, your extraction process may be contained within one such control area. Your isolation process may be contained within another. Bringing qualified and experienced architectural and engineering professionals to your team early can help you determine the MAQ for your materials and processes, and point the way toward the best and most cost effective design path for your facility.

When Control Areas Are Not Enough

If your facility and processing goals are large enough, you may require solvent and other hazardous material quantities that are greater than the MAQ allowed within building control areas. When this is the case, the entire building will need to carry a hazardous occupancy classification. Such a building will have increased setback requirements from property lines and...
will be subject to more stringent building, mechanical, and electrical code requirements. However, there will be no limits placed on the quantities of hazardous materials that can be used and stored in your facility. This can be a huge advantage for large extraction facilities. Here again, a qualified and experienced engineering team can help you navigate the stricter code requirements surrounding such a facility.

Room Classifications
The National Fire Protection Association (NFPA) code 497 addresses the classification of flammable liquids, gases, and vapors and of hazardous locations for electrical installations in chemical process areas, and has been adopted by most jurisdictions (1). Most extraction and refinement areas are classified as Class I, Division 1 (CID1) or Class I, Division 2 (CID2) spaces. NFPA 497 defines a CID1 space as a location "in which ignitable concentrations of flammable gases, flammable liquid-produced vapors, or combustible liquid-produced vapors can exist under normal operating conditions . . ." NFPA 497 defines a CID2 space as a location "in which volatile flammable gases, flammable liquid-produced vapors, or combustible liquid-produced vapors are handled, processed or used, but in which the liquids, vapors or gases will normally be confined within closed containers or closed systems from which they can escape only in the case of accidental rupture . . ." The essential difference between the two classifications is whether or not a flammable concentration of liquids, gases, or vapors can exist during the normal course of operation. By this definition, many extraction spaces will likely be categorized as CID2, but there are nuances that must be taken into consideration when selecting extraction equipment and locating that equipment within your extraction spaces. These nuances can have a considerable effect on your electrical design and can drive up your electrical construction costs if not dealt with properly.

Open Versus Closed Systems
Most jurisdictions will not allow open loop extraction systems because of the serious life-safety concerns they raise. But even closed loop systems can become "open" at certain times during the process. For example, what happens when you open the lid of your extraction vessel to remove the filter bags of spent hemp? The hemp still contains residual ethanol in small quantities, and that ethanol is now free to evaporate into the room. This constitutes an open system at that location, albeit only for a short period of
time. NFPA 497 provides guidance on how such situations are to be handled. See Figure 1.

In this example, opening the vessel creates a situation similar to the vent shown in Figure 1 from NFPA 497. Notice that there is a 3-ft. radius around the vent location that is classified as CID1, and an additional 2-ft. radius that is classified as CID2. Also note that the CID2 zone extends for a distance of 10 ft. at a height of 18-in. above the floor. Any below-grade locations within that zone become CID1. Understanding and applying this figure to the electrical requirements in an extraction room can have a major impact on the overall room design. For example, suppose your extraction vessel is on an elevated platform that is 5 ft. above the floor, and the vessel opens from the top 3 ft. above the platform. If the room ceiling is 12 ft. high, any lights over the vessel will have to be CID2 rated. A lower ceiling may require the lights to be CID1 rated, and there is a big difference in cost for CID1 lights. If the vessel is near a wall, then a portion of the wall will be within the CID1 and CID2 zones. Any outlets in those areas would have to be rated appropriately. What about other equipment located within the classified zones shown in Figure 1? Such equipment would be required to be rated for use in a classified environment, and the power connection to that equipment would also have to be so rated. Other equipment in the room may also create overlapping classified zones. It is apparent that great care must be taken when laying out equipment within an extraction room. Sometimes designers will default to declaring that the entire room must be classified as CID1 or CID2, but this is not required by the code, and can unnecessarily lead to increased construction costs. It is also worth noting that NFPA 497 contains many other diagrams that may apply to equipment in an extraction facility. An experienced engineering team can provide guidance in ensuring that your extraction room and all other control areas are properly designed to account for CID1 and CID2 zones within those spaces.

Final Thoughts
Understanding the various codes surrounding hazardous materials, control areas, zone classifications, and other critical factors that apply to designing and constructing an extraction facility can be a daunting task. Furthermore, code officials have the authority to interpret these codes as they see fit. Bringing the code officials into the design discussions as collaborators early on can have tremendous benefits for the project, saving time and reducing frustration. Engaging with an experienced and knowledgeable architectural and engineering team will facilitate working with the code officials to ensure compliance. They can ask the right questions and avoid serious pitfalls during the design and permitting process, and can work with you to ensure that construction goes as smoothly as possible.

References

About the Columnist
Rob James, PE, has nearly 30 years of mechanical engineering experience working on a diverse range of projects. His engineering experience includes a space launch complex, oil refinery, nuclear power plant, and building heating, ventilation, and air conditioning (HVAC) systems for hospitals, schools, dental clinics, veterinary clinics, churches, restaurants, offices, multifamily housing, retail, and industrial facilities. When recreational cannabis was legalized in Oregon, Rob applied his extensive experience to learning about this industry and its unique design nuances. Today, he has successfully designed HVAC systems for dozens of indoor grow and processing facilities in need of cannabis engineering.
Everything Old is New Again: Cannabis Returns to USP

The cannabis industry has been a hot topic of discussion over the last few years with the push for cannabis legalization around the world. It has been considered the most novel, brand new, and untested agricultural market in decades. But, what has been forgotten is that cannabis is not a new product, nor has it just appeared in the agricultural world. Cannabis was one of the largest agricultural crops in the United States up until its prohibition, and as such was a part of the United States Pharmacopeia (USP) compendium for almost a century. This column examines the history of cannabis in the US and the role the USP played in that field. We also discuss the new role the USP is taking in bringing the research and safety back into its scope including its most recent work and developments for the safety and quality of the cannabis for medical use.

Patricia L. Atkins

Despite the fact that cannabis is treated like the newest botanical product to come to market in decades, cannabis has a long-standing history going back before 3000 B.C. with the first recorded uses in China. Early cannabis products were hemp fibers and medicinal treatments were prescribed by ancient Greek and Roman physicians. In the 16th and 17th centuries the use of cannabis continued and increased with its expansion to the Americas in the 1600s.

Linnaeus classified Cannabis sativa in 1753 as other scientists and physicians included cannabis in world dispensatories. In the US, cannabis products were part of the history for centuries with even our founding fathers growing cannabis crops (Figure 1).

It has only been within the last 100 years that cannabis was consigned to the shadows of illicit and banned materials in the US and around the world. During the 19th century and the early 20th century, cannabis rose to widespread use, but also became the object of restriction around the world.

In 1906, the US Pure Food and Drug Act required labeling products that contained psychogenic substances such as cannabis and alcohol. By 1914, the Harrison Act (US) made the use of marijuana (a variety of cannabis that contains higher levels of tetrahydrocannabinol [THC]) and other narcotic drugs a crime. Starting in 1915 through the 1930s the prohibition and criminalization of cannabis continued all over the world. In 1937, the US Marijuana Tax Act criminalized cannabis without distinguishing between cannabis with psychotropic properties or species used for hemp products (1).

Despite its illicit status, the research into the medicinal uses of cannabis continued. Many medical applications have come to light and have been shown promising by the scientific methods, including its use as an analgesic for glaucoma and cancer patients. Now in the 21st century, countries around the world are rediscovering the beneficial and medicinal properties of cannabis and pushing for legality. Governments and regulatory agencies have begun to introduce or reintroduce cannabis into their catalog of botanical and agricultural products. One of the organizations actively involved in increasing our knowledge and understanding of cannabis is the United States Pharmacopeia (USP).

What is USP?
The USP is an independent, nonprofit organization outside of the US government whose purpose according to their missions statement (1) is “to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.”

The USP was founded in 1820 by physicians whose intent was to bring a national set of standards to the US that would unify the quality of drugs in the nation. At the time of the initial organization of the USP, most drugs were based on botanical or mineral ingredients. The US needed its own compendium or pharmacopeia (a compilation of standards and quality specifications that can test to confirm: composition, identity, purity, and strength of specified materials for use in medicines and food products) (2). The first national Pharmacopoeia of the United States of America (1820) contained a list of 217 drugs that included 145 botanicals and botanical products.

Subsequent editions of the USP...
Navigating the Labyrinth

Included updates, omissions, and additions of materials as research progressed or regulations changed. This process was observed in the case of cannabis, which first appeared in the 1850 edition of the USP until it was dropped from the pharmacopeia by 1940. The United States Pharmacopeia started as the primary compendium document produced from the USP Convention, which over the years has changed but persisted since its inception. The modern USP Convention is composed of three principle bodies: The Convention Membership, Board of Trustees (BoT), and the Council of Experts (CoE). The Convention is a group of up to 600 delegates representing academic institutions, health professionals, scientific and public interest organizations, state and national associations, agencies of the federal government, and many others. The Convention is governed by the Board of Trustees and advised by the Council of Experts.

The BoT assesses the proposed resolutions and shares the findings with The Convention. The BoT also makes the decisions about policy, finances, and the strategic direction of the organization. The CoE is elected to membership by the convention. Each CoE member serves as a chair for an expert committee for five years. The members share their knowledge, develop standards, and review the work plans for their committee. There are many groups and sub-groups within the USP CoE working on a range of topic groups for chemical analysis and dietary supplements (Figure 2).

The work cycle for the organization begins with the need for guidance, methodology, or standards for a new industry, product, or process (Figure 3). USP scientists and industry collaborate to draft a standard or guidance document. The draft is reviewed by experts and upon agreement posted for public review, which lasts 90 days. The comments and draft are then reviewed by the CoE and either approved or sent back for revision. Once approved the monographs, chapters, and other standards are published. Editions of the United States Pharmacopeia - National Formulary (USP-NF) are published on an annual basis. USP standards are reviewed regularly and revisions are published frequently.

The USP-NF contains two primary types of standard or information: monographs and general chapters. A monograph is a document that explains the expectations for a food, drug, or material to ensure its identity, purity, strength, and performance. Monographs contain the chemical information for the ingredient or material and outline the tests and procedures that must occur to meet quality criteria and limit impurities. There are more than 4500 monographs for prescription drugs, over-the-counter drugs, dietary supplements, medical devices, and other products found in the USP-NF.

A general chapter is a document that provides information on accepted processes, tests, and methods to support industry in product development and manufacturing quality controls. General chapters must be referenced in a specific monograph to be enforceable.
Challenges in the Cannabis Laboratory

on a legal basis. Otherwise, general chapters contain the best practices and methods for common processes or groups of analytical targets.

While the early editions of USP were always considered authoritative they were not officially or legally recognized in the US until a series of legislative acts: 1848 Drug Importation Act, the 1906 passage of the Food and Drug Act, and the 1938 Food, Drug and Cosmetic Act. The final act decreed that all medicines sold in the US must meet USP quality standards in what is now known as the USP-NF.

USP refers to both the United States Pharmacopeial Convention and the United States Pharmacopeia. The primary document produced from the USP is the compendium called United States Pharmacopeia. The United States Pharmacopeial Convention is the organizational body enacting the workings and standards of USP. In 1888 the National Formulary (NF) was created to complement and supplement the pharmacopeia. It is a compendium of formulations and includes standards for botanicals, excipients, and other preparations not found in the pharmacopeia. Over the decades the two compendia United States Pharmacopeia and the National Formulary merged in 1975 to be published under one cover called the USP-NF.

The full library of the USP documents, in addition to the USP-NF, include: the USP Compounding Compendium, Herbal Medicines Compendium, Dietary Supplements Compendium, and Food Chemicals Codex. Additional guidance materials are frequently published and disseminated by USP to cover emerging topics. These documents are publications such as general notices, articles, white papers, and informational guides.

More than 150 countries around the world recognize and use the standards published by USP. Despite its legal recognition by US agencies, the USP is an independent organization. The USP is an “organization of organizations” with its own governance and membership and broad stakeholder engagement that direct and inform their activities and produce guidance documents for food, pharmaceutical, and dietary supplement and herbal medicine industries which include botanicals.

The USP’s Role in Botanicals

The USP began in the early 19th century with the idea of standardizing substances and materials used medicinally in that time, which of course meant medicines based mostly upon natural botanical, biological, and mineral ingredients. It was recognized very early in history that agricultural and botanical products are prone to adulteration or substitution. In particular, it was believed that the US was often the recipient from world suppliers of low quality or counterfeited medicinal products which had little to no efficacy. Some botanicals were often adulterated or replaced for economic gain while other materials were unintentionally or intentionally misidentified or substituted (practices which still persist to modern times).

The Drug Importation Act (1848) was enacted to control the adulterated medicinal products entering the US. Later acts, as mentioned previously, continued to attempt to control the import, sale, and use of fraudulent and adulterated medicines. It became essential that standards and testing processes be implemented to confirm identity, potency, and safety of medications. Test procedures and physical reference materials developed over the history of USP became important benchmarks and industry standards for identity and quality of botanical products and dietary supplements in addition to the pharmaceutical products.

USP and Cannabis

As the botanical and dietary supplement industry changes and grows, additional methods, procedures, chapters, and monographs are added to the information provided by USP. In the last decade, one of the “newest” markets has been cannabis. But, as we have said previously, cannabis is neither a new product to the world or USP. During the 90 years that cannabis was documented in the USP, it appeared in many forms and iterations.

The first entry in 1850 was titled: “Extractum Cannabis. Extract of Hemp.” This form was an alcohol based extract of “Cannabis sativa – variety Indica” composed of the dried tops of the plants. USP V (1870) separated cannabis species into the flowering tops of C.
sativa grown in North America and the flowering tops of *C. sativa var. indica* from India. Cannabis extracts remained from contaminants such as mycotoxins, from the usual governmental sources. Cannabis extracts remained from India. Cannabis extracts remained from India. Cannabis extracts remained from India. Cannabis extracts remained from India. Cannabis extracts remained from India. Cannabis extracts remained from India. Cannabis extracts remained from India. Cannabis extracts remained from India. Now, in the US on the state level, cannabis has returned for medicinal use for more than 30 states, districts, and territories with more being added each year despite the continued federal status as a Drug Enforcement Administration (DEA) schedule I substance. The individual states have each applied their own differing approaches to the regulation of cannabis. Safety of the products is a goal, but one with lack of guidance from the usual governmental sources. Standards organizations, such as USP, have started to work to include cannabis into a dietary supplements and botanical guidance framework.

Since the reemergence of cannabis as a “medicinal” product, the goal for the USP is to help ensure the quality of cannabis intended for medical purposes and the development of quality parameters for authentication and identification. These will have to include: laboratory verification of cannabis identity; quantitative analysis of cannabinoids and terpenes; and limit exposure from contaminants such as mycotoxins, pesticides, and heavy metals.

The USP organized a multistakeholder roundtable in 2016 to discuss the path forward and subsequently formed a Cannabis Expert Panel to evaluate the specifications needed to define cannabis quality attributes and characteristics. Given the complex legal and regulatory landscape, it was decided early on not to focus on publication in an official compendium, but to ensure that scientific underpinnings of cannabis quality were disseminated as quickly as possible in a broadly accessible format. One of the first goals of the panel was the characterization and definition of a heterogeneous group of species and strains generally recognized as *Cannabis indica* or Cannabis sativa. Many scientists believe that the separation or designation of two species is not accurate in expressing the variation of chemotypes and characteristics found in the currently studied cannabis species and strains (3).

The panel published its recommendations in a peer-reviewed journal (5) and suggested that cannabis should be viewed as a single plant species, *Cannabis sativa*, with different strains (varieties) or subtypes differentiated based on chemotype profiles. The profiles divide cannabis into three main chemotypes based on amounts of THC and cannabidiol (CBD) with the groups being classified as THC dominant, CBD dominant, or intermediate with both THC and CBD (3,4).

**Cannabis Identification and Analysis**

The first step in proper description and control of quality is to establish a standardized nomenclature and identifying characteristics, then establish quantifiable concentrations or limits. Ideally, standardization of medical cannabis would be derived from plants of similar or identical characteristics and chemotypes. Over the centuries and with the advent of agriculture and selective cultivation and breeding, cannabis plants have evolved to produce variations of cannabinoid profiles which USP has suggested be placed into one of the three chemotype groups discussed.

The use of scientific analytical procedures is employed to identify and quantify the chemical marker compounds such as THC, CBD, and other cannabinoids or terpenes. Chromatographic methods such as high performance thin-layer chromatography (HPTLC), high performance liquid chromatography (HPLC), and gas chromatography (GC) are the most frequent tools for the separation, identification, and quantification of the cannabis marker compounds. Reference materials or physical standards, such as the ones currently produced by USP, can be used to confirm the identity of various cannabinoids by chromatographic techniques.

For these chromatographic methods, the USP has general chapters addressing the use of these techniques: *USP General Chapter <203> “High-Performance Thin-Layer Chromatography Procedure for Identification of Articles of Botanical Origin,” USP <1064> “Identification of Articles of Botanical Origin by High-Performance Thin-Layer Chromatography Procedure,” and USP <561> “Articles of Botanical Origin” (see Table I). Chromatography methods are also applicable in the determination of terpene compounds and ratios, which can be used in the identification of cannabis...
varieties (4). The USP Cannabis panel is suggesting analysis of the five most prevalent terpenes found in cannabis (one sesquiterpene: β-caryophyllene and four monoterpenes: D-limonene, β-myrcene, α-pinene, and γ-terpinolene) can provide valuable identity information. Each of these terpenes has appeared as the dominant or codominant terpene in various varieties of cannabis, which could aid in confirmation of identity.

Cannabis Safety Analysis

The ultimate goals for USP standards are to establish guidelines that ensure safety and create analytical limits for each type of possible contamination: pesticides, heavy metals, aflatoxins, and so on. General chapters give instruction on all aspects of testing and manufacturing quality control practices. These chapters are guidelines for the methodology, limits, and practices for pharmaceuticals, supplements, and botanicals to ensure safety of products. There have been multiple recalls of cannabis products over the past few years because of contamination issues.

Cannabis products are subject to all the same types of contamination found in other botanical and dietary supplement products: pesticides, heavy metals, aflatoxins, microorganisms, and so on. Pesticides are an often cited reason for cannabis product recall due to exceeding state limits or presence of restricted pesticides.

Cannabis plants are highly susceptible to infestations of a variety of pests including several molds, insects, and vertebrates (5). In the past and with the absence of legal guidance, cannabis growers used an assortment of pesticides, many not intended for use with food and medicinal crops. More recently, some cannabis product recalls have been cited for using unauthorized or banned pesticides not listed for cannabis use.

Typically, in the US, pesticides are regulated by the Environmental Protection Agency (EPA), but the restricted federal status of cannabis limits their involvement in cannabis pesticide applications. In this background, the USP presents guidance in the form of general chapters intended for botanical products. USP General Chapter <561> “Articles of Botanical Origin” establishes pesticide limits based on acceptable daily exposure, body weight, amount consumed, and a safety margin for oral exposure that can be used as a starting point for further development of pesticide residue standards for inhaled cannabis materials.

Toxic elements and heavy metals are another source of contamination in dietary supplements and botanical products. Cannabis is an effective concentrator of heavy metals. Impurities from environmental and other sources accumulate in the plant and then pose health risks for patients and consumers. For elemental impurities, USP has several chapters pertaining to heavy metal limits and testing, including limits for both dietary supplements (USP <2232>) and pharmaceuticals (USP <232>) (Table I).

Other chapters include standards for monitoring microorganisms and aflatoxins, which can be used to create limits and methodologies for cannabis testing around the world.
Final Thoughts
It has often been discussed and written that cannabis, especially at the start of the resurgence, was like the wild west with few rules and no guidance. The truth is that cannabis is a botanical product, like many other products, with a few unique challenges. Cannabis is neither a new botanical nor a totally unique one. The work of the USP over the past 200 years proves that fact. The analytical test methodologies, limits, and best practice guidance are being established by several standards organizations (USP, AOAC, ASTM, and others). These organizations often work in conjunction with each other, industry, and government to provide guidelines and standards to ensure the key components of identity, purity, and safety are met around the world for a wide range of products. Cannabis is only the latest product in need of guidance. USP has once again restarted the process to guide the cannabis industry into compliance as it has done in the past and will continue to do in the future. Additional work to research quality parameters for cannabis and derived products is currently ongoing at USP.

For more information on any of the USP chapters listed, or to volunteer to be involved in the workings of the USP process, please visit the USP website: www.usp.org/dietary-supplements-herbal-medicines/cannabis.

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About the Columnist
Patricia Atkins is a Senior Applications Scientist with SPEX CertiPrep and a member of both the AOAC and ASTM committees for cannabis.
A Tribute to the Life and Legacy of Charlotte Figi

A tribute piece to Charlotte Figi, an American girl with Dravet syndrome who took cannabidiol (CBD) oil to prevent seizures and inspired the name of the medical cannabis strain called Charlotte’s Web.

Cannabidiol (CBD), is now available everywhere—from grocery stores to gas stations. Millions of people around the globe use CBD to combat a variety of illnesses, disorders, and diseases. Yet many CBD users do not know that the awareness of the medical benefits of CBD, as well as their access to it, was due in large part to the heroic battles of a young, courageous girl named Charlotte Figi.

The cannabis industry has had many pioneers and trailblazers. We recently lost one of our greatest: Charlotte Figi, the young woman who became a hero in the CBD movement. On April 7, 2020 Charlotte passed away at the age of 13. Nichole Montanes, a close family friend of the Figi’s, posted a message on Paige Figi’s (Charlotte’s mother) Facebook page that read (1): “Charlotte is no longer suffering. She is seizure-free forever. Thank you so much for all of your love.”

We herein honor Charlotte and not only share her amazing story, but also explain the incredible inspiration that Charlotte has been to so many pediatric cannabis families.

Charlotte's Legacy

Charlotte and her twin sister, Chase, were born on October 18, 2006 to parents Paige and Matt and big brother Max. Charlotte suffered from Dravet syndrome. According to the Dravet Syndrome Foundation (2), Dravet syndrome is a rare catastrophic, lifelong form of epilepsy that begins in the first year of life with frequent or prolonged seizures. There are currently very limited options to treat Dravet syndrome. At the tender age of 5, Charlotte suffered up to 300 grand mal seizures a week and had extreme difficulty speaking.

Paige first searched for CBD oil in 2012 and Charlotte began taking high-CBD/low-tetrahydrocannabinol (THC) oil from the cannabis strain called “Hippie’s Disappointment.” This oil immediately reduced her epileptic seizures and the oil was later named “Charlotte’s Web” in her namesake. Her story was the focus of the CNN documentary Weed hosted by Sanjay Gupta in 2013 (3), bringing worldwide attention to the medicinal benefits of CBD, and making Charlotte a key figure in the medical cannabis movement.

Sanjay Gupta, in a statement shortly after Charlotte’s passing said (4), “Charlotte changed the world. She certainly changed my world and my mind. She opened my eyes to the possibility of cannabis being a legitimate medicine. She showed me that it worked to stop her crippling seizures, and that it was the only thing that worked.”

The Stanley brothers, who bred and commercialized Charlotte’s Web, the high-CBD/low-THC cannabis strain named after Charlotte, paid tribute to her on their website (5), stating: “Charlotte was ten feet tall and carried the world on her shoulders. Inspiring is a lacking word, as are courageous and vivacious and strong and beautiful. She was divine. She grew, cultivated by a community, protected by love, demanding that the world witness her suffering so that they might find a solution. […] Her story built communities, her need built hope, and her legacy will continue to build harmony.”

Charlotte inspired the medical cannabis revolution by championing the life-changing effects of CBD for patients with seizures and other debilitating illnesses and influenced legislation reform across the United States and worldwide. Congressman Matt Gaetz (R-FL) one of the leading GOP champions for broad marijuana reform on Capitol Hill, provided this statement on Twitter (6): “Charlotte lived a life of tremendous significance. Her story inspired me to completely change my views on medical cannabis and successfully pass legislation so that patients could get help in Florida.”

In addition to championing that CBD bill in Florida, a bipartisan congressional bill, “The Charlotte’s Web Medical Access Act” was named after her and introduced in 2015 (7).

Charlotte’s Influence

For this special edition of “Cannabis Crossroads,” I want to honor Charlotte not by reciting the legislation that she impacted, but by taking a closer look at the amazing influence and inspiration that she provided to so many pediatric cannabis families. These families became pediatric cannabis trailblazers themselves, forging ahead from inspiration drawn from Charlotte.

Gail Rand, whose son Logan was...
They got to ask questions and learn that ADHD at age two, spoke about how she first heard about Charlotte in June 2012 and her life was forever changed. “Her family’s willingness to share their story in a time where the stigma around medical cannabis was huge and the Federal government was still raiding many facilities was so incredibly brave,” said Rand. “Her mom, Paige, shared Charlotte’s story with Maryland legislators and regulators in a way that was incredibly powerful. They got to ask questions and learn that this is real medicine that could have a massive impact on Marylanders. For me, it is personal—my son is seizure free and I’m forever thankful to them for this.”

I also spoke with mother and daughter powerhouses, Janie and Rylie Maedler, about how Charlotte influenced them. Janie’s daughter Rylie was diagnosed with an extremely rare, aggressive giant cell granuloma in 2013. “Charlotte Figi was and still is an inspiration to me,” said Rylie Maedler. “Charlotte was living proof that cannabis can help treat those with severe untreatable epilepsy. She helped introduce cannabis as a treatment for pediatrics. Although Charlotte may not physically be with us now, what she accomplished will always be with us.”

“I know speaking as a mom that in your gut, you know what has to be done to save your child and this does away with fear,” said Janie Maedler. “Paige and Charlotte have given parents the strength they have needed to follow that gut. I’m forever thankful to them for this.”

Finally, I spoke to Moriah Barnhart whose daughter, Dahlia, was diagnosed with aggressive brain cancer at the age of two. “Sharing your child’s story in order to change public perception can come with stalling political, social, and psychological repercussions,” said Barnhart. “To embrace those repercussions while dealing with the daily struggles of caring for a severely special needs child takes unimaginable bravery and resilience. The life and death of Charlotte Figi embody the idea that suffering should not be in vain.”

**Conclusion**

In closing, I would like to share my deepest appreciation and gratitude to Charlotte and her family for advocating for their daughter’s healthcare and access to medicinal cannabis as a treatment, not only for their family, but for families all around the world. Charlotte has had a massive impact on the global cannabis community that will never be forgotten. The Figi’s are true pioneers that have opened so many minds about cannabis treatments with their advocacy and story sharing. Colorado Governor Jared Polis proclaimed April 7th, “Charlotte Figi Day” in Colorado. The loss of Charlotte Figi was felt around the world and she will be greatly missed by our entire community, but her legacy will live on forever and will continue to inspire many more individuals for years to come.

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**About the Columnist**

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Starting a QC Cannabis or Hemp Laboratory: Testing Requirements, Initial Expenses, and ROI

This article demonstrates how quickly a cannabis or hemp testing laboratory can see return on investment (ROI), despite a high initial investment in instruments and major consumables necessary to conduct key analytical testing. It provides information on the required instrumentation, approximate cost of the instrumentation, revenue per analysis, samples analyzed per week based on an 8-h day, break-even time after instrument purchase, and monthly expenses for major consumables.

Bob Clifford

As the cannabis and hemp industry expands worldwide, the need for quality control (QC) becomes even more essential to ensure continued growth. Just as foods and drugs are monitored to ensure accurate labeling and that they are free of contaminants, the same concept holds true with cannabis and hemp.

This testing requires a suite of analytical instruments. This article provides information on the required instrumentation, approximate cost of the instrumentation, revenue per analysis, samples analyzed per week based on an 8-h day, break-even time after instrument purchase, and monthly expenses for major consumables. The cost per analysis will vary based on location and should be verified. Information presented here is based on research in the US market.

This research does not provide details on building costs, rent, taxes, utilities, benches, ventilation systems, personnel, and so forth because there are too many variables. In addition, the expenses listed only include the more expensive items and not things like vials, caps, and certain other consumables. Also, it has been estimated that other laboratory supplies such as pipettes, gloves, vortexes, spatulas, cleaning wipes, dispenser for solvents, flammable solvent cabinet, and so on will require another $30,000.

Cannabinoid Profile Analysis

Cannabinoids are generally measured by techniques such as high-performance liquid chromatography (HPLC), ultrahigh-pressure liquid chromatography (UHPLC), liquid chromatography–mass spectrometry (LC–MS), and liquid chromatography–tandem mass spectrometry (LC–MS/MS).

UHPLC analysis times can be twice as fast as those using conventional HPLC, making it a more efficient technique, although it’s not as rugged as HPLC. Table I provides data when conducting a 10-min analysis of 11...
cannabinoids using HPLC. Increasing the number of cannabinoids to 15 will add 5 min to the analysis time.

For an 11-cannabinoid analysis, the revenue is typically in the $50–75 range, but Table I will use the lower $50 value because it is more prevalent according to research. With a run time of 10 min resulting in 48 samples per day, the revenue would be $12,000 per week, meaning the instrument will be paid off in less than one month. Table II provides a monthly cost of the more expensive consumables.

**Terpene Profile Analysis**

Consumers are very interested in terpene profiles because of the different aromas and possible medicinal benefits. The combination of terpenes and cannabinoids contribute to the “entourage effect” because of the synergy between these two classes of compounds.

Headspace–gas chromatography–mass spectrometry (HS-GC–MS) is one method for performing terpene analysis. With this method, the terpenes are separated from most of the 500 compounds in cannabis. The result is a clean spectrum because fewer compounds are being analyzed, which in turn leads to a longer column life.

Table III presents data for an analysis time of 12 min. This time could increase based on the number of terpenes being analyzed. It has been reported that there are more than 5000 terpenes in nature and 200 in cannabis, although most profiles analyzed contain fewer than 20. Revenue is typically in the range of $120 per sample. At 200 samples per week, the revenue will be $24,000 per week. The break-even point for the instrument is typically less than one month. The most prominent consumable is helium at $500/month. Adding vials and caps will bring the total monthly cost of consumables to approximately $1100. As mentioned earlier, because the sample is very clean, the column would only need to be replaced yearly.

**Heavy Metal Contaminant Analysis**

Food labels often contain nutrient...
information, such as sodium, potassium, calcium, and magnesium, which can be analyzed by inductively coupled plasma-mass spectrometry (ICP-MS). ICP-MS is also used to analyze toxic heavy metals, including the “big four” of arsenic (As), cadmium (Cd), lead (Pb), and mercury (Hg)—an analysis required by most states. In addition, various states require the analysis of other elements such as silver (Ag), barium (Ba), chromium (Cr), copper (Cu), iron (Fe), manganese (Mn), nickel (Ni), antimony (Sb), selenium (Se), and zinc (Zn). With ICP-MS, the analysis time is the same whether analyzing one or multiple elements because the technology can perform simultaneous analyses.

Expected revenue per sample is $75 for the “big four.” Analysis time listed in Table IV is 5 min, but there are accessories that decrease that time to approximately 2 min. The longer time was chosen because metals analysis is the fastest analysis in a cannabis or hemp laboratory and thus does not act as a bottleneck to obtaining a full certificate of analysis of all compound classes. Up to 480 samples can be analyzed per week for a revenue of $36,000. Return on investment (ROI) for an ICP-MS is less than one month.

Table V shows some of the more expensive consumable items, such as argon, a torch, and the cone assembly. The average cost of analysis is approximately $1/sample for all consumables.

### Residual Pesticide and Mycotoxin Contaminant Analysis

Since cannabis is illegal in the US on the federal level, the lists of pesticides, and their concentrations, to analyze vary by state. For example, while Oregon and California both include a high number of pesticides on their lists, the number varies, with 59 pesticides on Oregon’s list and 66 on California’s list. The maximum residual limit (MRL) values also vary within each state. Many other states follow the Oregon or California pesticide requirements, though most have made modifications. Canada has taken a different approach, requiring 96 pesticides to be analyzed and, in many cases, at much lower levels. As for hemp, though it’s federally legal in the US, there is no specific pesticide list. By Environmental Protection Agency (EPA) regulations, if a pesticide is not listed for a commodity, the default tolerance is set at 10 ppb as with any other agriculture product.

### Table V: Expenses for heavy metal analysis by ICP-MS

<table>
<thead>
<tr>
<th>Consumables</th>
<th>Amount</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argon (2 months)</td>
<td>Dewar</td>
<td>$530</td>
</tr>
<tr>
<td>Torch (3 months)</td>
<td>1</td>
<td>$425</td>
</tr>
<tr>
<td>Cone assembly (6 months)</td>
<td>1</td>
<td>$1400</td>
</tr>
<tr>
<td>Cost/sample over 1 year</td>
<td>—</td>
<td>$1</td>
</tr>
</tbody>
</table>

### Table VI: ROI for pesticide and mycotoxin analysis by LC–MS/MS

<table>
<thead>
<tr>
<th>8 H Day/5 Days a Week</th>
<th>Pesticides and Mycotoxins - ROI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected revenue/sample</td>
<td>$225</td>
</tr>
<tr>
<td>Total run time (min)</td>
<td>12</td>
</tr>
<tr>
<td>Samples/day</td>
<td>40</td>
</tr>
<tr>
<td>Samples/week</td>
<td>200</td>
</tr>
<tr>
<td>Expected revenue/week</td>
<td>$45,000</td>
</tr>
<tr>
<td>Instrument cost</td>
<td>$400,000</td>
</tr>
<tr>
<td>Break even (weeks)</td>
<td>8.9</td>
</tr>
</tbody>
</table>

### Table VII: Monthly expenses for pesticide and mycotoxin analysis by LC–MS/MS

<table>
<thead>
<tr>
<th>Consumables</th>
<th>Amount</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrogen</td>
<td>8</td>
<td>$740</td>
</tr>
<tr>
<td>Water/formic acid (LC–MS)</td>
<td>2.4</td>
<td>$300</td>
</tr>
<tr>
<td>Methonal (LC–MS grade)</td>
<td>2.4</td>
<td>$268</td>
</tr>
<tr>
<td>Extraction chemicals</td>
<td>16</td>
<td>$1848</td>
</tr>
<tr>
<td>Guard column</td>
<td>3/pack</td>
<td>$750</td>
</tr>
<tr>
<td>Analytical column</td>
<td>1</td>
<td>$750</td>
</tr>
<tr>
<td>Monthly total</td>
<td>—</td>
<td>$4656</td>
</tr>
</tbody>
</table>

### Table VIII: ROI for residual solvent analysis by HS-GC–MS

<table>
<thead>
<tr>
<th>8 H Day/5 Days a Week</th>
<th>Residual Solvent - ROI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected revenue/sample</td>
<td>$100</td>
</tr>
<tr>
<td>Total run time (min)</td>
<td>14</td>
</tr>
<tr>
<td>Samples/day</td>
<td>34.2</td>
</tr>
<tr>
<td>Samples/week</td>
<td>171</td>
</tr>
<tr>
<td>Expected revenue/week</td>
<td>$17,100</td>
</tr>
<tr>
<td>Instrument cost</td>
<td>$90,000</td>
</tr>
<tr>
<td>Break even (weeks)</td>
<td>5.3</td>
</tr>
</tbody>
</table>
Pesticides are generally analyzed by LC–MS/MS using electrospray ionization (ESI); however, atmospheric pressure chemical ionization (APCI) may be required depending on the regulations being followed. In some cases, APCI has replaced traditional GC–MS/MS methods. Since GC–MS/MS may be more sensitive for a few select compounds, consult your manufacturer about specific requirements. Pesticide analysis is generally in the $150–225 range per sample.

Mycotoxin ochratoxin A and aflatoxins B1, B2, G1, and G2 are required for cannabis analysis by many states. Typically, mycotoxin or aflatoxin revenue is approximately $75 per sample. Fortunately, pesticides and mycotoxins or aflatoxins can be analyzed in the same run using LC–MS/MS. The expected revenue for both compound classes is $225–300. In the example shown in Table VI, the lower value of $225 was selected. Up to 200 samples per week can be analyzed, resulting in revenue of $45,000 per week. At this rate, the break-even point on the most expensive instrument used in QC cannabis testing is approximately nine weeks.

Table VII shows examples of monthly expenses for operating an LC–MS/MS for cannabis analysis. Consumables include nitrogen gas, solvents, extraction chemicals, guard column, and analytical column. Monthly expenses will be under $5000 per month.

Residual Solvent Contaminant Analysis
Solvents are used to extract the cannabinoids and terpenes, and what remains on the product are referred to as residual solvents. Residual solvents are analyzed using a HS-GC–MS, the same instrument and autosampler used for the analysis of terpenes. Thus, only one instrument may be needed for both of these analyses.

Table VIII shows data based on an analysis time of 14 min for analyzing California’s 20 Category I and II compounds. Expected revenue is $100 per sample. At a rate of 171 samples per week, the weekly revenue would be $17,100, and break-even would be about one and a half months. Expenses are like those described earlier under terpenes.

Moisture Balance and Water Activity Meter
All analytical measurements described earlier require an analytical balance. Another type of balance is a moisture balance. Moisture balances can help improve the accuracy of analytical techniques, since results are determined on a dry weight basis. Also, if the moisture content is above 12%, the product is prone to mold growth. Some states also require water activity meters, especially for storage of product, to prevent mold growth.
Shown in Table IX is the ROI based on revenue of $20/sample and an analysis time of 10 min. Measuring 240 samples per week results in a weekly revenue of $4800, meaning the balance is paid off in less than half a week.

**Pathogen Analysis**

Most states require measurements of six pathogens, including pathogenic E. coli, Salmonella, and four species of Aspergillus: A. fumigatus, A. flavus, A. niger, and A. terreus. These are detected using microarray technology. Typically, revenue is $80 per sample. If analyzing 240 samples per week, the weekly revenue will be $19,200 with a break-even point of two and a half weeks as shown in Table X.

Expenses for pathogen analysis are shown in Table XI. The consumables are more expensive than for other technologies. The table also includes data for a laboratory technician working 2.5 h per day at $30/h. Monthly revenue for four weeks would be $76,800, and expenses would be $31,308 for net of $45,492.

**Conclusion**

This article demonstrates how quickly a cannabis or hemp testing laboratory can see ROI, despite a high initial investment in instruments and major consumables to conduct key analytical testing including HPLC and HS-GC–MS for cannabinoids and terpenes as well as residual solvents, ICP-MS for heavy metals, LC–MS/MS for pesticides and mycotoxins, and microarray technology for pathogens. Also discussed are analytical balances, moisture balances, and water activity meters. Variable expenses related to geographical location are not included as the information would be exhaustive for this article. The ROI calculations are intended for general reference only; Shimadzu does not guarantee testing volumes nor prices.

**References**


Dr. Robert (Bob) Clifford

received his bachelor’s degree from Glassboro State College, now Rowan University, in New Jersey, his master’s degree from Villanova University in Pennsylvania, and his PhD from George Washington University in Washington, D.C. He has published and presented more than 125 papers in the fields of food, pharmaceutical, environmental, energy, geology, material science, photonics, and cannabis. He has been with Shimadzu Scientific Instruments in Columbia, Maryland, for 28 years in a variety of roles. He currently serves as general manager of marketing. Direct correspondence to: rclifford@shimadzu.com.
THE POWER OF THE SPECTRUM

Enriching Cannabis Plants with Spectrum

To only feed a cannabis plant with high-pressure sodium (HPS) light or pink LEDs is like only eating carbohydrates—without a comprehensive diet that includes proteins, fats, and other nutrients, you’re at high risk for undernourishment. Same goes for cannabis. Good artificial lighting improves upon sunlight and drives the cultivation of a healthy plant, rich in secondary metabolites such as tetrahydrocannabinol (THC) and cannabidiol (CBD). Growers with long-standing experience in cultivation have amassed a wealth of methods to get their desired end product. But finding quality lighting isn’t easy. Amid the many LED companies featuring exorbitant and confusing claims, there are reputable lighting producers, such as Finland-based Valoya, that although its name is not well-known, it boasts the largest patent portfolio in the cannabis-lighting industry. Its established customer base consists of crop scientists, vertical farmers and plant wall, greenhouse, and algae cultivators. The value of Valoya’s patented spectra has been recognized over the past 10 years by hundreds of businesses in over 50 countries.

High-Quality Light Produces High-Quality Plants
A spectrum is a delicate resource that is unmatched in power by any other cultivation resource a grower has at their disposal. The balancing act of constructing a spectrum includes manipulating the colors, ratios, and intensities to find the sweet spot that makes the cannabis plant happy. Having performed cannabis trials since 2015 with world-renowned Dr. Gianpaolo Grassi of the Italian Council for Agricultural Research and Economics (CREA)-Ci institute, Valoya is the only LED company in the world whose biologist’s name is among the authors of a cannabis-focused academic article in a peer-reviewed journal (Med Cannabis Cannabinoids. 2018;1:19-27). And after three years of development, it launched Solray®, a spectrum that outperformed HPS and LED counterparts in trials, in terms of cannabis plant biomass and chemical composition.

To UV or not to UV?
The cannabis plant likes a lot of light, and it benefits from a spectrum that includes UV. LED manufacturers avoid UV LED chips because they are expensive and require glass protection, as plexiglass and silicone burn under them. A balanced amount of UV provides gentle stress to the plant, which facilitates the creation of secondary metabolites as its defense mechanism. In practice, this means the plants will be compact, thus capable of supporting large flower formations and will be covered in cannabinoid-saturated resin.

Harnessing the Light
Although Solray spectrum outperformed other PS and LED lights, it doesn’t mean the research stops. Using Vayola’s LightDNA, researchers can explore the possibilities of light and engineer any spectrum conceivable to further advance the cultivation of cannabis and other crops. LightDNA is the most advanced application of LEDs in horticulture, with eight different spectra. In simple terms, it is an LED lamp that can replicate outdoor sunlight (within the 380 – 780 nm range with an accuracy of 90% or higher) to indoor growing environments from any part of the world at a click of a button. The user can customize location (What part of the world do you want to mimic light patterns from?), duration (days, hours, etc.), and more. This tool gives researchers the power to channel light from anywhere in the world—a power they have not yet had in their growth chambers—fulfilling Vayola’s mission of “advancing agriculture and photobiology to make food and medicine production more efficient for the growing global population.”

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28% more flowers

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Getting Started with GxP Compliance in Your Cannabis Laboratories and Facilities

Any company that is involved in the cultivation, harvest, processing, analytical testing, storage, packaging, distribution, wholesale, or selling of cannabis is subject to regulatory inspections (depending on which country you operate in or distribute to), and like the rest of the pharmaceutical community adhering to good laboratory practice (GLP), good clinical practice (GCP), good manufacturing practice (GMP), and good distribution practice (GDP). Even if national regulations aren’t in place in the US, there are US state requirements, and strict regulations in some European states. From a business standpoint, ensuring quality control of temperature-sensitive cannabis products will decrease risks such as product quarantine, invalid test results, patient side effects, and ensuing legal issues. Put bluntly—your cannabis business won’t stand the test of time in this exploding industry if your practices are not GxP compliant—from laboratory to clinical to distribution. In this article, you will learn about the GxP requirements for laboratories, production facilities, and distribution of cannabis.

Benoît Chedhomme

The supply chain of a cannabinoid product resembles that of a pharmaceutical product. Quality must be maintained throughout source of ingredients, testing in laboratories, production processing, and carefully packaged and transported products.

If quality is compromised at any step, the result will be an inferior product that jeopardizes your business, consumer trust, and, most importantly, the health of the patient. One of the most critical risk points is for laboratories storing reagents and samples in refrigerators. Like any machine, performance of a refrigerator can vary and expire. Thus resulting in a temperature deviation that could influence the results of the analytical testing.

Regulations: US
As of March 2020, 33 US states have laws allowing medical use of cannabis, plus another 14 allow the use of low tetrahydrocannabinol (THC) limited programs. In addition, 11 states also allow recreational use or “adult use” (see Figure 1). For a comprehensive state by state overview of legalized medical and “adult use” cannabis use, visit the National Conference of State Legislatures web page on marijuana laws (1).

One key good practice (GxP) standard guidance in the US is from the United States Pharmacopeia General Chapter <1029> “Good Documentation Practices” (2), that states:
- Records should be clear, concise, accurate, and legible
- Data entries should be recorded promptly when actions are performed
- No backdating or postdating
- Documentation system is needed to ensure data integrity and availability of current and archived records

Regulations: Canada
Documentation is key. As per section 231 of the Cannabis Regulations (3–5), license holders (other than cannabis drug license holders) must maintain records demonstrating their adherence to the good production practices (GPP). License holders must be able to demonstrate, using records available at the licensed site, that the activities conducted are compliant.

Have you faced a regulatory audit yet? In Canada, they started in 2017 following three recalls of cannabis for medical use related to the unauthorized use of pest control products (PCPs). Health Canada began a series of unannounced inspections and targeted testing of cannabis products from licensed producers under the Access to Cannabis for Medical Purposes Regulations to ensure that only authorized PCPs were used during the production of cannabis. Later that year, Health Canada announced it would require mandatory testing for the presence of pesticide active ingredients in all cannabis products, before the products could be sold or provided to individuals.

Regulations: Europe
There is no harmonized European Union (EU) law on cannabis use. The criminal or administrative response to drug use offences is the responsibility of EU Member States, not of the EU. For example, in 2017 the national German legislature expanded the options for prescribing medical cannabis
products by passing a law amending provisions under the Narcotics Law and other regulations. These products, however, must comply with the relevant requirements laid down under the Medicinal and Narcotics Law, including good manufacturing practice (GMP) and good distribution practice (GDP). Therefore, the Federal Institute for Drugs and Medical Devices (BfArM) has taken over new responsibilities by establishing the Cannabis Agency. This agency is meant to help in ensuring supplies for medical-quality cannabis.

Since medical cannabis is considered a pharmaceutical product in all of Europe, all products must fully comply with GMP. In addition, all products must be certified by the International Organization for Standardization (ISO) both in the country in which it is produced as well as from an EU authority.

According to EudraLex: The Rules Governing Medicinal Products in the European Union, Volume 4, Good Manufacturing Practice Medicinal Products for Human and Veterinary Use (6) areas should be designed or adapted to ensure good storage conditions. It states (6), “In particular, storage areas should be clean and dry and maintained within acceptable temperature limits. Where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored."

What is GxP?
GxP is the broader umbrella for good laboratory practices (GLP), good clinical practices (GCP), GMP, and GDP. These are sets of standards designed by regulatory agencies to control the quality and licensing for the development, manufacture, and distribution of food and drug products. Each country has their own set of GxP guidances, but overarching global agencies such as the World Health Organization (WHO), Pharmaceutical Inspection Convention (PICs), and others strive to harmonize national regulations.

GxPs and a company’s quality management system (QMS) go hand in hand. A QMS is the backbone of a company to ensure all processes and policies are focused on consistently, meeting customer requirements. In the market of human medicines, customer requirements equate to the safety, efficacy, and quality of the medicinal products. A scientifically sound and well validated QMS helps a company meet GxP guidelines. So, what do each of these mean in the cannabis industry?

GLPs for Cannabis Analytical Laboratories
GLPs ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of a chemical that is created or modified in any laboratory intended for human use.

Before cannabis is packed, labelled, and sold, legal producers have to prove that pesticides are within acceptable limits. Independent laboratories use extraction techniques to make sure that the cannabis does not go over the allowed limits of pesticides set by state or regulatory standards. The list of pesticides and the chemicals to be tested is huge, often more than 100, and acceptable limits are usually very low. Combine that with the fact that plants are grown in the earth and as a result, will have some residual levels of pesticides.

What does that mean? This is a very expensive part of the cannabis business! Tests can cost an average of $1000 per test. For hundreds of pesticides against the set standards, that adds up quickly. As an example, there is a list of pesticides and standards set out by Health Canada available online (7).

Proper storage in refrigerators is imperative to protect the financial value of the stock and products. In addition, GxP requires documentation that proves temperature control while in the refrigerator, in process at the laboratories, and through distribution to the consumers.

Old technology that so many laboratories still use for monitoring refrigerators or other laboratory equipment (such as chart recorders) can put GLP, and cannabis products, at risk. Manual processes for checking temperature graphs, storing paper, and writing deviation reports is subject to human handling errors. Read more about why chart recorders are not the right choice to protect your financial investment in the cited literature (8).
GMPs for Cannabis Manufacturing and Processing Facilities

GMPs are a system of procedures and documentation for the proper design, monitoring, and control of manufacturing processes and facilities to ensure each product has the identity, strength, quality, and purity that it is represented to possess. GMPs cover all aspects of production processes, personnel, and facilities:

- Materials
- Premises
- Equipment
- Storage
- Record keeping
- Staff training
- Hygiene
- How complaints are handled
- Product development

GMPs state all facilities must be environmentally controlled including temperature, humidity, and light for the storage and use of materials and products. You need to ensure products won’t freeze in winter, or bake in the attic in the summer. This means you need to temperature map that facility to learn where the hot and cold spots are, then create your monitoring program around that.

A temperature mapping study is used to measure and document the temperature distribution within a room by locating the hottest and coldest spot. According to WHO (9), “mapping may also be used to identify zones where remedial action needs to be taken; for example by altering existing air distribution to eliminate hot and cold spots.”

According to GMPs, new facilities must always undergo a mapping exercise, but there are instances that require a remapping of facilities, and these include: heating, ventilation, and air conditioning (HVAC) modifications, significant warehouse layout changes, extensions to facilities, and sometimes even new product lines will warrant a mapping exercise.

Keith Konya, Sr. Manager of Facilities at Express Scripts/CuraScript, learned a few good lessons by going through the mapping exercise. “We identified three hot spots which were caused by heaters blowing directly on pallet locations,” said Konya. “The heaters have been repositioned as well as pallet locations removed from service.”

GDPs for Cannabis Supply and Distribution

GDPs entail quality procedures and standard operating procedures (SOPs) that ensure consistent storage, transport, and handling of temperature sensitive products throughout the supply chain. That means even when it leaves your possession as a legal producer, your transport partners must be in compliance as well with your product quality control requirements. GDPs include:

- Qualification and validation of facilities, systems, and partners
- Deviations and changes
- Responsible persons
- Documentation and records
- Warehouses—mapping and monitoring
- Transport qualification
- Outourced activities
- Complaints, returns
- Counterfeit and recalls
- Self-Inspection

In the GMPs section above, we discussed mapping and qualification of facilities. What about while the product is in-transit? How are you monitoring temperature control along the fragmented way? Cold chain monitoring solutions such as USB data loggers, temperature indicators, and other technology can give you peace of mind that the quality of your products is monitored after manufacture and through the supply chain.

There is a free booklet on how to navigate GDP guidelines online (10) as well as a blog post titled “GDPs – Not for the Faint-Hearted” (11).

First Steps to GxP: Temperature Mapping

Each environment is going to be slightly different. In laboratories, you will need to evaluate your refrigerators, freezers (if any), and cool rooms. For your distribution operations (GDP), you will evaluate your current warehouses, facilities, transport vehicles, and boxes used for shipping.

Let’s use the example of GLP, for an analytic testing laboratory. In a laboratory, you will need to measure the environments of the rooms where the testing is conducted, and the refrigerators where the materials are stored (see Figure 2).

First, you will set up a business case to implement GLPs. This is done by assessing your current infrastructure and equipment, involving your different departments (quality, IT, finance), and quantifying financial loss if something went wrong.

Once you have a business case for why GLPs are important for your business, then you will develop user requirement specifications (URS) defining the project goals. Next, defining the layout of your laboratory facility is used to determine an implementation plan with measuring points.

A mapping study takes place for a defined time period, typically a few days or weeks, and monitors temperature in various defined locations inside the room (for example, refrigerator, warehouse, box, or container) forming the mapping grid. The mapping grid follows two principles:
The hottest and coldest spots are obvious places to install sensors of the monitoring solution, since a temperature excursion at those spots would be most critical first and therefore measured first.

System Considerations
To monitor the environmental conditions of your products in refrigerators or using a central monitoring system, there are many different types of monitoring solutions that could work. Some questions to consider include:
- Wired or wireless?
- Dedicated network or WiFi?
- Cloud or local hosting?
- Local or remote alarms?
- What kind of alarms?
- Remote access
- Centralization for several sites or buildings (worldwide)?
- Other specific needs: Write down your “must have,” “should have,” and “must not have.”
- Leave space to comment on each requirement.
- Are all of systems user friendly? What does it mean for you?

Conclusion
Regulations exist to protect patients. Although they are resource intensive, they will continue to increase, having a resounding impact to your cannabis business. As state and eventually national requirements get stricter, your business will be set to avoid product recalls, negligent product quality policies, and possible legal action if you are GxP compliant.

Companies who get on board now, will have a significant advantage over those that try to retool their processes and SOPs later. GxPs also help build your company’s reputation and quality brand in this massively growing and competitive industry.

If the GxP requirements seem daunting, there is a lot of help out there ranging from ex-regulatory consultants to specialty firms in environmental monitoring. The point is, just get started. The early adopters of the practices used by pharmaceutical companies will be ahead of the regulatory curve and be best positioned for success in the market.

References
10) https://www.research.net/r/CB92J9J

Benoit (Ben) Chedhomme supports life science companies to protect their temperature sensitive products from cold chain failure. His main expertise is on validation of facilities or equipment and temperature monitoring for storage and transportation. Benoit also performs many compliance assessment projects for pharmaceutical companies to evaluate the different options that could be implemented to reach regulatory compliance. Benoit is currently the Canadian Territory Manager at ELPRO, who provides monitoring for small laboratories with standalone equipment, as well as multi-national projects requiring cold chain monitoring, thermal mapping, and facility monitoring systems. Direct correspondence to: Benoit.Chedhomme@elpro.com

Madeline Colli

In April 2020, Cannabis Science and Technology announced its partnership with the American Chemical Society’s (ACS) Cannabis Chemistry Subdivision (CANN) (1). The partnership began with an event called the “Spring 2020 CANN Virtual Symposium,” which took place May 6–7, 2020. The symposium featured several sessions over a two-day period that had originally been organized for the ACS Spring 2020 National Meeting & Expo scheduled for March that was cancelled because of the COVID-19 global pandemic.

“We are honored to be able to partner with CANN and the ACS during this uncertain time to help transition their National Meeting & Expo into an innovative virtual symposium,” said Mike Hennessy Jr., president and CEO of MJH Life Sciences™, the parent company of Cannabis Science and Technology™. “As our partnership grows, we look forward to working together with them to further their mission and educating the cannabis community.”

Over the two-day virtual symposium, speakers ranging from researchers, cannabis scientists, and industry experts presented more than a dozen lectures on a large variety of topics. A highlight of the virtual symposium were the presentations from all of the 2020 ElSohly Award winners—Justin Fischedick, PhD, Integrated Analytical Solutions; Sang Hyuck-Park, PhD, Institute of Cannabis Research; Jiries Meehan-Atrash, Department of Chemistry, Portland State University; Markus Roggen, PhD, Complex Biotech Discovery Ventures (CBDV); and Jacqueline von Salm, PhD, AltMed—which kicked off the first session called “The 2nd Annual ElSohly Award Symposium.”

The 2nd Annual ElSohly Award Symposium

The ElSohly Award creates a platform for students, researchers, and other industry experts to present their findings and was the first ever cannabis chemistry award. It is awarded once per year to highlight some of the exciting findings taking place in the cannabis industry.

Dr. Justin Fischedick presented first and detailed an overview of the historical research of cannabis terpenes in his talk titled “Terpenoids of Cannabis sativa L., Analysis and Applications.” Fischedick used gas chromatography to analyze and identify the cannabinoids in his samples. Through his presentation, he hoped that attendees would walk away with a better grasp on the literature out there regarding cannabis terpenes.

“I find a lot of information regarding the analysis of terpenes in cannabis that is easily accessible online is coming mainly from the cannabis industry or instrument vendors,” said Fischedick (2). “The information coming from both of these sources while sometimes useful can also be misleading regarding the most appropriate analytical technique or potential medicinal or therapeutic effects of these compounds.”

Dr. Jacqueline von Salm followed next with her presentation titled, “Unique Terpene Metabolites as Descriptors of Unique Cannabis Phenotypes and Products.” The overview of her talk focused on terpene metabolomics of in-house cultivars and what terpenes highlight the similarities or differences between phenotypes.

“Other groups have also done this research, but as with any chemical ecology type studies, environment is so important for chemical production,” said von Salm (2). “Our chemovars show a specific terpene that has largely been ignored in cannabis is a major differentiator among phenotypes. This terpene isn’t even regularly tested by third party labs!”

Through various extraction, cultivation, and production techniques, there are many items that can affect the composition of cannabis products. Von Salm hopes that her research brings new questions and commentary to the cannabis industry.
Jiries Meehan-Atrash’s talk was titled, “Chemistry of Cannabis Terpene Degradation.” Meehan-Atrash explained that his talk dealt with some experiments he performed recently that were one of the first times that isotopic tracing was used to study the degradation chemistry happening in e-cigarettes, and certainly the first time it’s been applied to cannabis vapes. “The Strongin group is one of the few that studies the degradation of e-cigarette components mechanistically, looking at the bigger picture to help guide future efforts,” said Meehan-Atrash (2). Through his work, Meehan-Atrash hopes that the research will show what additives to products can be dangerous to one’s health.

The next talk was called “Collaborative Research for Fundamental Insight into Cannabis Production” and was presented by Dr. Markus Roggen. Roggen briefly discussed the basics of cannabis before delving into his research that focused on data analytics of cannabis extraction and predictive algorithm developments for extraction optimization such as decarboxylation. Through his findings, Roggen hopes that attendees take away from his research that there is still so much to do, and that we need help from every scientist in the field (2).

Closing out the ElSohly award presentations, Dr. Sang-Hyuck Park’s talk was titled, “Defensive Role of Cannabidiol (CBD) Against Pest Insect Tobacco Hornworm Manduca sexta Through Disrupting Exoskeleton Development.” Fascinated by CBD, like many scientists, Park wanted to explore the other benefits of CBD aside from its therapeutic effects. “For my talk at the CANN symposium, I will primarily focus on the defensive role of CBD against the pest insect, tobacco hornworm Manduca sexta, and how CBD deters the insect feeding behavior as well as inhibiting their growth and development,” said Park (2). Through his research findings, Park learned that CBD is used to protect the cannabis plant from pest insect infestations due to its quality to act as a repellent.

Advances in Cannabis Policy, Products, and Personal Use

The second session of the virtual symposium was titled “Advances in Cannabis Policy, Products, and Personal Use.” It covered various cannabis topics such as federal policies, legalization status, and how personal biochemistry can be used to inform medical uses.

Beginning the afternoon session, Tami L. Wahl’s talk titled “A Modern Industry Redefining Federal Policy” provided a history of the cannabis market on the state and federal level. States that have legalized cannabis, have found success in their state-regulated markets. The industry helps create jobs, tax revenue, efficiency in treatments of medical conditions, and Wahl also found that there is no data currently that indicates increases in social harms.

Len May followed up next with his talk called, “The Scientific Matchmaker, DNA and Cannabis: Your Genetics May Influence Your Experience with Cannabis and CBD.” He began by briefly going over the endocannabinoid system and how no individual will have the same experience. May also discussed the endocannabinoid DNA test his company built that will help users treat their medical conditions and know what works best.

Next “Edibles: Chemistry Behind Orally Consuming THC” was presented by Samuel Adam. His research focused on the effects of edibles on the human body. He walked attendees through the cycle of ingesting tetrahydrocannabinol (THC) orally and then how the body works on breaking down and absorbing the cannabinoids. Adam also highlighted the differences between cannabis consumption methods such as smoking and edibles and why they produce different effects depending on how THC is absorbed through the body.

Closing the first day, David Vaillencourt presented his talk called “Employing a Risk-Based Approach During Development of Cannabis Products.” Vaillencourt discussed developing the first laboratory standard for cannabis test method validation and how to develop a risk-based approach during the development of cannabis products. A main focus was making sure instructions are followed throughout the process, reiterating that by doing so you could save a life.
Breakthroughs: New Pathways for Cannabis Analysis

The final session in the Spring 2020 CANN Virtual symposium was called “Breakthroughs: New Pathways for Cannabis Analysis.” The session focused on analytical chemistry, for example, new detection methods for cannabinoids and molecular kinetics of cannabinoid decarboxylations. Benoit Lessard began with his talk titled “On-the-Spot Detection and Speciation of Cannabinoids Using Organic Thin-Film Transistors.”

Lessard’s presentation started with an overview of traditional and organic electronics. He researched organic thin film transistors (OTFT) and found that they are an effective platform for detecting chemical analytes. By using these OTFT sensors, cannabinoids can be easily detected and differentiated. Lessard hopes that with the continuation of his research he will be able to explore other areas of the cannabis plant and variables, such as dried, field, oils, hemp, and edibles.

Next up was Amber Wise who presented, “Development and Optimization of Test Methods for Macro and Micro-Nutrients in Both Fresh Sap and Dry Cannabis Sativa Leaves Using ICP-MS and Microwave Digestion.” Wise used one detection method (microwave digestion) for two separate projects that were specialized between fresh sap analysis and dry leaf analysis. Through her research, Wise believes that growers should be using the data she learned to help optimize nutrient and fertilizer applications which will aid in diagnosing issues.

“Vaping-Induced Lung Injury and Vaping Chemistry” was presented by Robert M. Strongin. He wanted to investigate emerging cannabis products and their effects. Strongin discussed what happens to cannabinoids when concentrates are vaporized or dabbed. He found that the vaping industry had either assumed or oversold the safety of their products. Strongin hopes that through his research, usage of these methods will decrease, preventing harm to the lungs.

Closing out the virtual symposium, Meagan Bauer, an undergraduate student at Northern Michigan University, discussed her research in Dr. Brandon Canfield’s laboratory through her talk titled, “Holding the Center: Kinetics of Cannabinoid Decarboxylation and Decomposition.” They researched the Cannabis Sativa L. strain’s two most popular cannabinoids: tetrahydrocannabinolic acid (THCA) and cannabidiolic acid (CBDA). In their experiments, they used pure THCA and CBDA and then placed them into different solvents where they were heated. Using different solvents, the experiment was repeated and then analyzed using liquid chromatography–tandem mass spectrometry (LC–MS/MS). Bauer and the group found that CBD appeared to be capable of conversion to THC under relatively moderate conditions (acidic).

Conclusion

Over the two days of the Spring 2020 CANN Virtual Symposium, all three sessions were very well attended and had great audience participation. The next CANN conference is tentatively planned for the ACS Fall 2020 National Meeting & Expo from August 16–20 in San Francisco, California. Cannabis Science and Technology (CST) is excited to continue working with CANN on future events and partnerships.

“CANN greatly looks forward to its partnership with CST to continue to drive these initiatives of information sharing,” said Julia Bramante, chair of CANN and lead scientist for the Marijuana Reference Laboratory of the Colorado Department of Public Health and Environment (1).

To watch the Spring 2020 CANN Virtual Symposium, please register for the free on-demand viewing on our website (3).

References


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A Chemist’s Guide to the COVID-19 Outbreak

The COVID-19 pandemic has created a plethora of misinformation regarding viruses, transmission, eradication, and prevention. This information brief is an attempt to organize all of the pertinent information from a chemistry point of view.

Patricia Atkins and Rebekah Biermann

The COVID-19 pandemic has created a plethora of misinformation regarding viruses, transmission, eradication, and prevention. Outbreaks of disease which have led to pandemics have been frequent throughout history, including the smallpox outbreaks which decimated the Incan empire in the 1500s to the more recent SARS pandemic and the Ebola epidemics in the past decades. It wasn’t until the first electron microscopes that the actual virus structures were observed in the 1930s. Since those early discoveries, there have been more than 5000 additional viruses detailed with millions more still uncharacterized in the environment.

What Are Viruses?
A virus (Latin for poison) is a very small infectious agent that can only replicate inside living cells of another organism (microorganisms, plants, and animals). Most viruses can range in size from 20–300 nm (Figure 1). In essence, viruses are parasites that cannot live and replicate outside host cells. Viruses lack the cellular organelles and processes to survive and replicate on their own. The host cell’s replication system is hijacked by the virus and produce viral replication material.

Virus Structure
Outside of a host cell, viruses are independent particles called virions. There are three basic parts to viruses: the genome (genetic material—either deoxyribonucleic acid [DNA] or ribonucleic acid [RNA]); the capsid (a protein capsule surrounding the genetic material); and in some cases, a lipid or protein outer envelope. Viruses can be found in a variety of shapes, from simple to complex. There are four morphological forms of viruses: icosahedral, spherical, helical, and complex (Figure 2). The viruses can also vary in size from under 50 nm to over 900 nm in length (helical or filamentous viruses). The COVID-19 virus is a new virus that is part of the
Coronavirus family (Coronaviridea). The coronavirus was named for the Latin for crown because the projections (spike proteins) on the surface of the spherical virus look like points on a crown (Figure 3). The coronaviruses have a membrane enveloping the capsid and are in the middle to large range of the virus size scale at around 100 nm.

The coronavirus contains RNA genetic material rather than DNA. RNA viruses have higher mutation rates than DNA viruses because the enzymes, which catalyze RNA replication (RNA polymerases), lack the ability to proofread or error correct the genetic material being coded unlike DNA and DNA polymerases. This reason is why these types of viruses mutate so quickly and are difficult to create vaccines to combat.

Viruses, Disease, and Health

Most viruses are species-specific, meaning an equine virus does not spread to a human. However, there are zoonotic viruses that can spread between animals and humans. In some cases, a virus can mutate and jump to other species, which seems to be the case with the COVID-19 virus.

In most cases, viruses are infamous for being instigators of disease, but viruses can also be used to combat illness and diseases, such as cancer by hijacking the cellular reproduction of cancer cells. Viruses are also instrumental in human health. It is well known that humans have beneficial bacteria in their body. Another resident of the human microbiome are viruses (called the virome). The virome inhabits humans within the first months of life. Each person has a unique virome. Retroviruses are RNA viruses that change the genome of the host cell. The host cell then incorporates the new genetic material into its own code when it reproduces. Endogenous retroviruses, viruses that originate within an organism, tissue, or cell, are prevalent in humans (up to 8% of our genetic material) (1). These viruses were once considered junk material, but have been discovered to have a role in human health. In a recent study, it was hypothesized that since humans diverged from chimpanzees, up to 30% of protein adaptations have been due to viruses (2).

Viral Infections

Each type of virus can enter a host cell in a different process. SARS and COVID-19 attach to receptors on host cell surfaces that can result in membrane fusion, which allows the virus to penetrate the host cell. Once inside the host cell, the capsid is degraded by enzymes or dissociation and releases the viral genome into the host cell. Once inside the cell, the genome hijacks the genetic replication machinery of the host cell and produces more copies of the virus.

Individuals who are shedding the virus are contagious. Some viruses have symptomatic shedding where the person is infectious upon showing symptoms or shortly before showing symptoms. Viruses with asymptomatic shedding or a silent infectious period are contagious for a longer period of time before or if symptoms occur. COVID-19 can have asymptomatic shedding, resulting in infections being transmitted without the carrier knowing they are infected. The time line of an infection starts with the exposure of an uninfected individual to the virus. As the virus infects the host cells and replicates there is a period of incubation where the virus is latent. At some point during
incubation, the first infected host cells begin to shed virus particles and begin the infectious period. This period may or may not include symptoms as was stated previously (Figure 4).

The rate at which viral infections increase is dependent upon several risk factors including: population density, geography, sanitation, age, sex, immunity, viral stability, virulence, ease of replication, and mode of transmission. Geography determines if a virus can reach the stage of an outbreak, epidemic, or pandemic. An outbreak is a localized number of infections beyond normal for the area. An epidemic is an increased number of infections in a larger geographical area than in an outbreak. Finally, a pandemic is the spread of an infection over several countries or continents. Geographically isolated areas have a better ability to contain outbreaks. The relatively easy access and world connectivity of the outbreak center for the COVID-19 outbreak in Wuhan, China made it difficult to contain, thus it spread into an epidemic and then a pandemic.

Viruses increase rapidly in areas of high density, which is why it is recommended to limit the size of groups and practice social distancing during outbreaks, epidemics, and pandemics. This strategy reduces contact rates, which are the rates at which an infected individual is in contact with other people. Individuals in high density living arrangements, cities, or professions have a higher contact rate and have a higher incidence of exposure to infected individuals or infecting others. Two other factors in rates of infection are the mode of transmission of a virus and the basic reproduction number ($R_0$). The mode of transmission of a disease is the way in which a disease causing agent is transferred from an infected individual to another uninfected individual. A virus can be transmitted via direct physical contact or indirect physical contact.

Direct physical contact includes sexual contact, kissing, or exposure to secretions and usually occurs within friends, households, or families. Indirect physical contact can be contamination from physical surfaces. The COVID-19 virus has been shown to spread through direct contact with infected oral and nasal fluids and through indirect contact on surfaces where droplets of the virus can be deposited. The COVID-19 virus can live from several hours to several days on various surfaces. The half-life of a virus is how long up to half of the virus initially deposited will remain viable and the viability is the amount of time in total viable virus particles can be detected (Table I).

Additional modes of transmission include airborne or droplet transmission from coughing, sneezing, and breathing. Viruses can be transmitted by poor hand washing or sanitary conditions in which fecal matter infects food or water sources. Finally, viruses can be transmitted from other organisms or vectors such as flies, mosquitoes, or an intermediate host.

The number of individuals on average that an infectious individual will expose to a contagion is called the basic reproductive number or $R_0$ (pronounced R naught). The higher the value, the more infections will result from exposure. COVID-19 currently has an $R_0$ value of 2–5 (this value is constantly changing as the pandemic progresses). Some common diseases such as Measles and Whooping Cough are highly infectious with $R_0$ values over 10 (Table II).

Basic reproduction numbers are calculated on a population without any immunity. If a population has some immunity, then less people will become infected and if a population is vaccinated, increasing the population immunity, then the virus is not able to spread efficiently. COVID-19 is a new virus and the population at large appears to have little natural immunity from it. There were also no vaccines available to treat the population to increase immunity at the time of the start of the pandemic.

A vaccine is a biological preparation of potentially infectious disease that can impart immunity to the disease. The process of creating a new vaccine can take anywhere from months to years. There is the possibility that the vaccine is developed for a strain that
has dramatically mutated into another resistant form before the vaccine is ready for distribution.

**Vaccine Production**
The development of a vaccine is a complex multistep process (4) (see Figure 5):
- **Exploratory**: research to identify and study antigens for prevention or treatment. This stage includes genetic material extraction from the virus and replication using polymerase chain reaction (PCR).
- **Preclinical**: tissue or cell cultures and animal tests are used to determine if a potential vaccine will produce immunity. It is during this phase that most vaccines fail to produce either immunity or are harmful to the test subjects.
- **Clinical development**: approval by the US Food and Drug Administration (FDA) for three or more rounds of human trials. Each round of analysis includes the safety of the proposed vaccine, immunogenicity, immunization schedule, dose, size, and overall effectiveness.
- **Regulatory review and approval**: upon passing of vaccine, it is subject to regulatory review and approval by the FDA.
- **Manufacturing**: mass production of vaccine
- **Quality control**: quality control that monitors performance and safety by the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink

**Stopping Transmission of Viruses**
As a disease progresses from an initial outbreak to an epidemic it becomes important to use policies to contain and slow the spread of the disease before it hits pandemic proportions. In other historical outbreaks, it was easier to contain viral outbreaks due to limitations of travel and geography. In our modern world, however, our international community and ability to travel easily and frequently has only aided in the spread of COVID-19.

The essential methods of dealing with an outbreak or pandemic is a multi-pronged attack to limit exposure by isolating those infected, keep risk of exposure to a minimum for the uninfected, practice good health and hygiene practices, develop and employ effective viricides to stop transmission and alleviate symptoms, and develop prophylactic measures such as vaccines to stop future emergence. The Centers for Disease Control and Prevention (CDC) has issued guidelines for limiting exposure for the general population (Figure 6) (6).

The second line of defense is for all individuals to practice behaviors to protect themselves and others, such as practicing social distancing, wearing masks, and practicing good hygiene practices.

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### Table I: COVID-19 persistence on surfaces (3)

<table>
<thead>
<tr>
<th>Surface</th>
<th>COVID-19 Viability (Hours)</th>
<th>Half-Life (Hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerosols</td>
<td>3</td>
<td>1.2</td>
</tr>
<tr>
<td>Copper</td>
<td>4</td>
<td>0.8</td>
</tr>
<tr>
<td>Cardboard</td>
<td>24</td>
<td>3.5</td>
</tr>
<tr>
<td>Stainless steel</td>
<td>72</td>
<td>5.6</td>
</tr>
<tr>
<td>Plastic</td>
<td>72</td>
<td>6.8</td>
</tr>
</tbody>
</table>

### Table II: Common viruses, modes of transmission, and basic reproduction number ($R_0$)

<table>
<thead>
<tr>
<th>Virus</th>
<th>Mode of Transmission</th>
<th>$R_0$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measles</td>
<td>Airborne</td>
<td>12–18</td>
</tr>
<tr>
<td>Pertussis</td>
<td>Airborne droplet</td>
<td>12–17</td>
</tr>
<tr>
<td>Chickenpox</td>
<td>Droplet</td>
<td>8–9</td>
</tr>
<tr>
<td>Rhinovirus (cold)</td>
<td>Airborne or transfer</td>
<td>5–7</td>
</tr>
<tr>
<td>Polio</td>
<td>Fecal-oral route</td>
<td>5–7</td>
</tr>
<tr>
<td>Smallpox</td>
<td>Airborne droplet</td>
<td>5–7</td>
</tr>
<tr>
<td>COVID-19</td>
<td>Airborne droplet</td>
<td>3–5</td>
</tr>
<tr>
<td>SARS</td>
<td>Airborne droplet</td>
<td>2–5</td>
</tr>
<tr>
<td>AIDS</td>
<td>Body fluids and sexual contact</td>
<td>2–5</td>
</tr>
<tr>
<td>1918 influenza</td>
<td>Airborne</td>
<td>2–3</td>
</tr>
<tr>
<td>Seasonal influenza</td>
<td>Droplet</td>
<td>1–2</td>
</tr>
<tr>
<td>Rabies</td>
<td>Saliva</td>
<td>1–2</td>
</tr>
<tr>
<td>Ebola</td>
<td>Body fluids</td>
<td>1–2</td>
</tr>
</tbody>
</table>
limit exposure, which includes cleaning of common areas, hand washing, and isolating oneself when sick. The laboratory approach to the COVID-19 crisis should follow the same advice but expand to encompass the laboratory space, equipment, and personnel.

In the laboratory, social distancing and not gathering in groups translates into several policies such as:

- Staggering work schedules and changing to shifts
- Work from home (WFH)
- Stop travel and in-person meetings
- Limited contact from outside vendors, sales people, visitors, and food delivery

Cleaning and Disinfecting in the Laboratory

The first step in disinfecting a laboratory is general cleaning. Dust and dirt attract and collect particles of mold and viruses. After general cleaning, the process of disinfection can then occur. There are many commercial products for all types of settings from home to healthcare and laboratory. Most of these products have familiar active chemical agents such as alcohols, acids, chlorides, and so on.

The mode of action for these products is usually one of the three processes:

- Dehydration: the virus or biological agent is dehydrated by a chemical and rendered inactive
- Cell disruption: denaturing proteins or dissolving lipid capsules allow spilling of viron contents out and inactivation
- Process inhibition: disrupts genetic, protein, or amino acid processes and inhibits replication

The Environmental Protection Agency (EPA) has published an extensive list of all of the commercial products for use in cleaning against viruses and COVID-19 on their website (8). The European Union (EU) has also provided guidance on agents that have been tested against viruses in the Coronavirus family with their concentrations for use (Table III) (9–10). Instructions on use and dilution of common laboratory chemicals such as ethanol, sodium hypochlorite, and more can be found on the disinfection pages of the CDC for healthcare settings (11).

The common theme for all of these disinfectants is that the product must be applied and allowed to disinfect for a period of time before being wiped away (dwell or contact time). There are very few instantaneously effective products and in most cases the solution needs to be applied for up to 10 min before wiping or washing the surface clean to ensure proper disinfection.

An additional method of sanitization is the use of heat and steam. Temperatures from 75 °C to 100 °C are best for disinfecting viruses. These methods reduce the risk of chemical contamination from commercial or laboratory-based cleaners, but do have risks for moisture sensitive laboratory areas or chemicals. It is important to remember in the use of cleaners and cleaning agents that they are still chemicals capable of contaminating daily processes and operations. Additional actions may be needed to ensure normal laboratory processes are not contaminated by the updated cleaning procedures. Before cleaning and disinfecting an area, all porous materials such as paper, paper towels, and so on, should be removed from the areas to be cleaned so as not to absorb chemicals. Select cleaning agents appropriate for the area to be cleaned with thought in mind as to the type of work that occurs in these areas and how that work will be affected by these agents. If possible, airflow and hood flow should be increased to drive fumes away from work areas. Chemical odor traps can be used to absorb volatile chemical fumes. Hoods and sensitive areas should be decommissioned during cleaning and allowing several hours for fumes to dissipate.

Personal cleaning and hygiene plans and expectations should be discussed or notices posted to remind everyone to keep a cleaning plan. One of the most important acts a person can do to reduce their exposure is to wash their hands for a minimum of 20 s with soap and water. Most soap compounds are composed of materials whose molecules have a dual nature: hydrophilic
end and binds to polar solvents such as water and lipophilic end binds to long hydrocarbon chains, proteins, and lipids. The action of the soap and water together allows for viral particles to become bound to the soap's lipophilic structure and allows water to wash the particles away after the appropriate dwell time of at least 20 s (Figure 7).

**Personal Protective Equipment**

Most laboratory personnel are familiar with common laboratory personal protective equipment (PPE), but there are some differences in equipment and use that one often takes for granted as correct. There are different uses for each type of PPE and different ratings for equipment such as masks, respirators, gloves, and so forth, which are dependent on the function they are intended for in the laboratory. There are some specialized PPEs that are only used in specific settings that tend to benefit the laboratory's clean setting rather than the laboratory technician.

Items such as sticky mats, shoe covers, and clean rooms stop the transfer of particles (dirt and otherwise) to and from locations. In chemistry laboratories, these items are used mostly to protect the laboratory from added contamination. In a hospital or healthcare setting these items can also protect the environment from the transfer of contaminated particles outside a quarantined or contaminated area. Clean rooms or controlled quarantine rooms have sealed air flow and ventilation with high efficiency particulate air (HEPA) filters to reduce particle transmission.

Most clean rooms are rated by the amount and size of particles that are filtered by the system. Respirators, face masks, and face shields cover different parts of the face but generally cover the mouth and nose. Face shields offer the least amount of respiratory protection since they are only physical barriers to splashes and respiratory expulsions directed at the face. Respirators filter particles, chemicals, and fumes depending on their specification using filtration chemicals or materials. Respirators are meant to protect the wearer from these agents and must be properly fitted and tested by a professional to ensure good seal and appropriateness for use. Face masks can also potentially be a tool for the filtration of particles depending on their rating. Fitted face masks are very different from the surgical masks being seen in pictures during this outbreak. All of the world organizations warn that a generic face mask is not a substitute for a fitted and regulated face mask or respirator (13,14).

During the COVID-19 pandemic, the use of N95 respirators is often called for and requested. These particle respirators trap up to 95% of particles. For more information, refer to CDC, Occupational Safety and Health Administration (OSHA), National Institute for Occupational Safety and Health (NIOSH), and International Organization for Standardization (ISO) guidelines and instructions on selection and use of respirators and masks.

It is more common that chemists and other laboratory scientists use basic PPE such as goggles, glasses, gloves, and lab coats. All of these PPE items are needed for chemical protection, but can also be used for protection against biological agents. As with the respirators, there are different classes of goggles, glasses, and gloves that are dependent upon use.

Goggles and glasses protect the eyes from splashes and can be made from a multitude of materials resistant to a range of agents. Gloves as well can be made from a variety of materials, which is important to understand since each type of glove has its own strengths and weaknesses. Many gloves are subject to issues of chemical or biological resistance meaning not all materials are resistant to all agents and therefore offer limited protection. Resources such as online databases for glove compatibility are available (15).

The choice of the proper PPE is not the only factor in protection for the wearer. The matter in which PPE is put on and removed after use is important. Many laboratories or healthcare settings have isolation PPE procedures for strict quarantine and contamination control. Smaller commercial laboratories with lower risk for infection often have simple, if any, procedures for proper PPE use. There are some tips to help use PPE efficiently.

Gloves must:
- Be compatible material for the purpose
- Fit snugly but not so tight that they stretch and become compromised more quickly during use.
- Not gap at the fingers.
- Be removed to limit exposure and contain contamination such as by pulling one glove off with the still gloved hand and then using the inside portion of the glove to remove the second glove folding them into each other so the glove disposal packet has the contaminated or exposed areas contained inside the packet.

Lab coats must:
- Fit properly and button.
• Have cuffs that do not hang down into the work area nor are too short to not cover the tops of the gloves when worn.
• Pockets should not contain items that cannot be exposed to contamination or infection such as personal phones.
• Be changed frequently.
• Removed similar to the gloves in the contaminated area.

In the event of a known viral exposure, all PPE items and trash should be isolated from the common waste stream and disposed of in a separate location.

Conclusions
During this time of heightened anxiety, it is good to know most common laboratory procedures used to keep scientists safe from chemical exposures also work well for limiting biological exposures. More diligence must be paid in common areas and with common touch points in our offices, laboratories, and lives. Check on all of the protective equipment used in the laboratory and make sure it is up to the task that is being set. Isolate all potential contaminants and dispose of them quickly. Most importantly, use your knowledge, training, and understanding of science to promote calm and educate your coworkers, employees, families, and others of the real facts of infectious diseases and prevention. For more information and details see the full technical note “A Chemist’s Guide to the COVID-19 Outbreak” (17) or the on demand webinar (18).

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5) Cole-Parmer: coleparmer.com

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The Legal Cannabis Coalition: A Closer Look at How Dutch Horticultural Companies and Scientific Partners Joined Forces

Dr. Arno Hazekamp, cofounder and board member of Legal Cannabis Coalition as well as the director and founder of Hazekamp Herbal Consulting, discusses the formation, goals, research, and education initiatives going on in the newly formed group.

Megan L’Heureux

Recently, the formation of a group called the Legal Cannabis Coalition (LLC) was announced (1,2), which consists of a dozen Dutch horticultural companies. During the past two years, these companies participated in a joint scientific study to optimize greenhouse cultivation of medicinal cannabis that was organized by Wageningen University & Research (WUR) in The Netherlands. Here, Dr. Arno Hazekamp, cofounder and board member of LCC as well as the director and founder of Hazekamp Herbal Consulting, discusses the formation, goals, research, and education initiatives going on in the newly formed LCC.

Can you tell us more about the LCC? How did it form and what are the goals of the group?

Arno Hazekamp: The LCC started as a group of individual companies that offer products and services to the horticultural industry. Each company is a leader in its own field, for example, building greenhouses, installing light-emitting diode (LED) lights, and supplying ventilation or climate control systems. Dutch greenhouse growers are well known for their productivity and quality, making The Netherlands the second largest exporter of fruits and vegetables in the world! And these service providers are an important part of that success. So, when the cannabis industry started growing rapidly in recent years, it was no

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Arno Hazekamp: The LCC started as a group of individual companies that offer products and services to the horticultural industry. Each company is a leader in its own field, for example, building greenhouses, installing light-emitting diode (LED) lights, and supplying ventilation or climate control systems. Dutch greenhouse growers are well known for their productivity and quality, making The Netherlands the second largest exporter of fruits and vegetables in the world! And these service providers are an important part of that success. So, when the cannabis industry started growing rapidly in recent years, it was no
surprise that Dutch companies became involved with cannabis producers all over the globe. But with more business come more questions, and we all know how many different approaches there are to cultivating cannabis indoors. That’s why these Dutch specialist companies decided to join forces, and initiate a research project to systematically and scientifically determine the optimal growing conditions for various cannabis strains, in collaboration with the top-rated agricultural University of Wageningen (WUR). This research project started almost 3 years ago and is still ongoing, so the participants got to know each other—and their products—very well.

As for myself, I was asked to join the scientific advisory board for the cultivation research in 2018 and it has been a great learning experience. Last year we realized that our cultivation research may someday come to an end, but we wanted our collaboration to keep going. That’s when we decided to collaborate in an industry association we called the Legal Cannabis Coalition. It means we are working as a coalition of independent companies, with a focus on legal (licensed) cannabis projects around the world. We invited several members with expertise in laboratory and pharmaceutical development because medicinal cannabis involves much more than only growing the plant. With the current list of members, we feel that we can support almost any customer question, based on experience, collaboration, and our own research data.

How much collaboration is involved from the various parties in the LCC?

Hazenkamp: The LCC currently has 16 members with a variety of backgrounds. Most LCC members got together through collaboration in the WUR cultivation experiment I already mentioned. That means every month we come together to discuss the results of the cultivation experiments so far, and decide on the set up of experiments to come. This includes discussions about new varieties or new technologies that have become available for cannabis cultivation, but also about laboratory testing, drying technologies, or packaging. We also coordinate our visits to cannabis conferences and events, and we discuss the business questions that are starting to flow in now that the LCC has been officially started. And, most importantly, various members work together on cannabis projects around the world. Most projects require inputs from several service providers at once, and we believe that we can provide the best advice when working as a group. So when a new licensed producer (LP) wants to build a greenhouse, set up their own laboratory, and develop a new type of cannabis product, the LCC will bring all the relevant members to the table at once. In that way, the client can talk to everyone in one go, and find one integrated solution to their problem, instead of shopping around and dealing with individual providers one at a time. Our members know and trust each other, and they are actively comparing strategies to give the customer the best service possible. Our intention is to make the LCC a one-stop shop for anyone in the cannabis industry, but also to provide services to researchers, government, and pharmaceutical companies.

What kind of educational efforts is the LCC doing?

Hazenkamp: The LCC is focused on sharing reliable information about cannabis, both within our group of members and outside. Internally that means we train our own staff to become more familiar with all aspects of the cannabis industry. In that way, our greenhouse builder understands a bit of laboratory testing, and our laboratory knows about the challenges of cultivation. This creates mutual understanding between LCC members, which will lead to better solutions for our customers.

We also provide training and education for others. For example, last year we helped to develop an e-learning course for physicians and other healthcare professionals in The Netherlands. By working together with a well-known organization in the field of medical training (Dutch Institute for Rational Use of Medicine [IVM]), we created a 2 hour online course that was certified for continued medical education (CME) credits. It has quickly become one of the most popular training modules offered by IVM, reaching hundreds of healthcare providers. Each year, I personally organize the Masterclass Medicinal Cannabis, a one week intensive course for a small group of selected students. And I am involving the members of the LCC as speakers in the course. By interacting with the international participants of the Masterclass, the LCC members are not only teaching but also learning at the same time. We plan to organize the next Masterclass in collaboration with the province of New Brunswick, Canada. We have built up some great ties with cannabis companies and academics over there, and together we call ourselves the New Brunswick-Netherlands (NB-NL) network.

How will the LCC’s research efforts impact other cannabis research or help the industry develop further?

Hazenkamp: A noticeable characteristic of the cannabis industry is that it does not share much information. In this highly competitive business, problems are rarely admitted, all information is treated as intellectual property (IP), and new findings are
The various members of the LCC have for themselves and the same mistakes can be made over and over again. The various members of the LCC have been involved in many cannabis projects that sometimes went right and sometimes wrong. As a result, we believe we have the collective knowledge to help others to prevent making those same mistakes. Another big source of information comes from our WUR cannabis cultivation trial, mentioned before. Because the LCC is not producing cannabis for the market, we have been able to freely experiment with a wide range of parameters to learn more about what makes cannabis grow well. I believe our trial may be one of the biggest cannabis cultivation studies ever done. Through the LCC members, this information will become available to customers, so they can make more fact-based decisions. Also, with more partners we can do larger and more interdisciplinary studies. We don’t grow and sell cannabis ourselves, we just help others. So our goal is not to collect IP and hog information, but to help others to make better choices. That means we actively want to share and teach. One of our current projects is to create an international platform for student training, exchange, and internships with our partners in New Brunswick. In this way, we strive to educate the next generation of professional workers for the cannabis industry.

What is the biggest challenge facing cannabis cultivators? Are there unique challenges for medicinal cannabis cultivators?

Hazekamp: In my opinion, the greatest challenge is the lack of standardization in the cannabis market: Countries allow different types of cultivation (indoors versus outdoors) and products (medical versus recreational), the rules are different everywhere, and even procedures for laboratory testing are not generally agreed upon. Many cannabis companies treat all their knowledge as IP so nothing gets shared. And new inventions are not presented in scientific papers (which allows for peer-review), but in advertisements. In such an environment it is going to be hard to agree on what a “quality” product actually is. You can see this most clearly in the cannabidiol (CBD) market: many studies from all over the world indicate that CBD products often don’t contain the amount of CBD listed on the label. Some products don’t even contain any cannabinoids at all. I have been involved in several of these studies myself. And it seems unclear who is responsible for this situation, because everyone points to someone else.

The same issue can be seen with medical professionals, who are used to work with highly standardized medicines. Although medicinal cannabis is now legal in more countries than ever before, most physicians will still not actively prescribe it. Cannabis is so far outside their image of what is a standardized and trustworthy medicine, that physicians simply reject it completely. So, what we need is a common agreement on how to measure quality, composition, and medical effects. That starts with cultivation, and ends with proper, independent laboratory testing. We all know that if you send the same sample to multiple laboratories, you get back many different testing results. For the cannabis industry to grow successfully, these inconsistencies have to be dealt with.

I believe this problem is indeed unique to the cannabis market, because for any other type of product (food, medicines, consumer electronics, cosmetics) there are clear agreements on what quality is. But because cannabis has a unique history, it falls between all these categories: it is a novel food, herbal medicine, and recreational drug all at once. Authorities are starting to realize that this is creating a mess, and are working on stricter demands at the level of the World Health Organization (WHO), US Food and Drug Administration (FDA), European Union (EU), and so on. You can see this most clearly with CBD, which is rapidly becoming a Novel Food in Europe. I strongly believe it is better to agree on your own (industry) standards quickly, before the authorities come in and tell you what to do. And that means working together on a much larger scale then the industry has done so far.

How did you get started in cannabis research? Can you tell us more about some of your most recent medical cannabis research endeavors?

Hazekamp: I personally started my cannabis research in 2001, at Leiden University in The Netherlands. I was a pharmacy student with an interest in medicinal plants, and one day my professor asked me if I would like to do a PhD focused on cannabis. My first response was: sure, but why? I was told that the Dutch government was setting up an official medicinal cannabis program, so that patients had access to high quality cannabis and did not have to visit their local coffee shop anymore. So suddenly, I was the very first Dutch PhD student looking at medicinal cannabis, in one of the world’s first cannabis programs. I got my plant materials from the Dutch licensed producer Bedrocan, and had access to a university pharmaceutical laboratory with the most amazing technologies. I also had a cannabis license that allowed me to do virtually all laboratory research I could think of, valid for 5 years. I am certain that no one in the world had more possibilities to study cannabis than me,
at that time. My thesis (finished in 2007) became a very well read reference guide for cannabis researchers around the world, and then I started working as the head of R&D at Bedrocan for the next 10 years. During my studies, I helped to set up quality control methods, isolated my own cannabinoid standards, defined the differences between sativa and indica, developed the Volcano vaporizer as a medical device, and was the first scientist to look at Simpson oil. But I also had many experiences outside the laboratory, such as helping to design clinical trials, perform international patient surveys, and study the prescription of medicinal cannabis by Dutch physicians. Altogether, my career has given me a very broad experience with medicinal cannabis use.

In recent years, my attention mainly went to analyzing the quality of CBD products. In a world where everyone has an opinion about cannabis, it is important to keep doing smart and reliable studies and provide data that can help with decision making.

**What has surprised you the most in your cannabis research?**

Hazekamp: As a scientist, I am always trying to find support for my ideas, to collect data, and then think about how this data could be even better and stronger. When working for commercial companies, there is always a bit of tension between the scientists (we need more research) and the sales department (we need more sales). And in a healthy company these two forces are in balance. What strikes me about the cannabis industry, is how many people take a minimal scientific fact, and turn it into a completely new product, without actually understanding how it works, or how it should be made. Many bad CBD products are made by business people who heard about CBD, but don’t actually know much about it. And although many people have the experience of growing cannabis plants for themselves, doing it for medicinal use is a completely different game. And some folks running a cannabis laboratory, obviously do not understand the basics of analytical chemistry. As a result, I have had many discussions with people who produce and sell cannabis products that do not live up to their promise. I like to call this cannabis myth-busting, or “canna-busting.” Of course, I do believe in the medicinal powers of cannabis, but I am also worried that “cannabis cowboys” may ruin it for all of us. So I often confront businesses with their own claims, and simply ask them: can I see your data? How do you know this? I have exposed many myths in this way, and I like to believe that this helps the industry move in a better and smarter direction. These experiences also help me to tell great stories when I meet with policymakers and authorities, and help to get higher quality standards established.

**What are you next steps in cannabis research and education? How does the LCC fit into those plans?**

Hazekamp: Education has always been one of my favorite parts about working with cannabis. After all, there is so much to say and learn about this topic. I prefer to have a class full of people for several days, with a range of interesting speakers that stick around for long discussions and deep questions. Exactly like we do at the Masterclass Medicinal Cannabis. In this way you create a truly inspiring learning environment, where students also dare to share their worries and problems, instead of only successes and wins. Those are the moments when real bonds are created. At conferences you can also meet amazing scientists, but there is never sufficient time for questions, and good luck trying to chase down your favorite presenter during the lunch break. Of course, the success of any course depends on the quality of its speakers. So what could be better than having access to leaders in their field, who you know up close, and who you can trust based on projects that you work on together. The members become the teachers, and we can even initiate research projects together, like we are currently doing with WUR, if there is a gap in our knowledge. That’s why it is so important that multiple LCC members have a research license for cannabis. It allows us to put our own questions into research. For myself, the teaching I did was mainly based on my own research experiences in the laboratory, and outside. And because I was sharing my own personal experiences, the teaching got better and more involved. With a much wider network like the LCC, we will be able to study, and teach, so much more from our own collective experiences. And perhaps, after teaching is done, some of the more talented students may become our new employees. In that way, our courses will become a fishing pond for future talent.

**Reference**


2) www.legalcannabiscoalition.nl/

This interview has been edited for length and clarity. To read the full interview with Dr. Hazekamp please visit: www.cannabissciencetech.com/topic/cannabis-voices.
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