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As the pharmaceutical industry continues to maneuver through the pandemic, pharmaceutical companies and contract manufacturers are working together to develop preventive vaccines and monoclonal antibodies to treat COVID-19 patients. This activity is happening in addition to the industry’s usual work in developing and manufacturing medicines for other health conditions. Pharmaceutical Technology’s Buyers’ Guide provides you with information on suppliers of ingredients, materials, equipment, and other resources needed to develop, manufacture, and distribute solid dose, parenteral, biologic, inhalation, transdermal, and other drug forms.

This year’s Buyers’ Guide also features case studies on current industry topics such as artificial intelligence, new drug development, extractables and leachables, prefabricated cleanrooms, custom products, tumbler blending, data management, and eliminating particulates. These insights can be found in the Case Studies section beginning on page 123.

In the coming months, we will also be launching our new enhanced online eDirectory, https://pharmtechbuyersresource.com. This new platform will offer you the latest supplier information to help you choose the resources necessary to deliver crucial medicines to patients.

We hope this print guide and the upcoming enhanced online directory serve you well as you make the important decisions needed to have a successful business. PT
For vendor contact information, see Company Directory section.
This new informational General Chapter — GC <1469> — provides detailed analytical methodology and criteria for analyses to evaluate nitrosamine levels. In combination with USP Nitrosamine Reference Standards, GC <1469> can help control for nitrosamine impurities in drug substances and drug products and describes:

- A risk-based approach for the control of nitrosamine impurities to manage their presence in drug products
- Robust analytical procedures with suitable levels of detection and quantification of target nitrosamine impurities
- Compliance with FDA standards

USP is responding to the nitrosamine impurities challenges by providing tools and solutions — like GC <1469> — so you can feel confident in monitoring impurities in the drug supply chain.

**Discover the value beyond the vial.**

View more information about GC <1469> at [https://www.usp.org/chemical-medicines/nitrosamine-impurities](https://www.usp.org/chemical-medicines/nitrosamine-impurities)
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Kavon Filter Products Co
Karine-Sanderse
Pall Corp
Steri Technologies

FILTERS, AGITATED
3V TECH USA
Chem Floxtronics
GMP Systems
Heinkel
Jaygo
Karine-Sanderse
Pall Corp
Steri Technologies

FILTERS, CAKE WASHING
3V TECH USA
Avery Filter Co
Bopp USA
Eaton Technologies GmbH
ERE
GMP Systems
HEMCO Corporation
Jaygo
Kavon Filter Products Co
Karine-Sanderse
Steri Technologies

FILTERS, CONTINUOUS
Eaton Technologies GmbH
GMP Systems
Karine-Sanderse
Meissner Filtration Products
Steri Technologies

FILTERS, DISPOSABLE
Eaton Technologies GmbH
GMP Systems
Karine-Sanderse
Steri Technologies

FILTERS, Hollow-Fiber
GMP Systems
Pall Corp

FILTERS, MAGNETIC
Erop USA
Eriz
GMP Systems

FILTERS, MEMBRANE
Avestin
Eaton Technologies GmbH
G-M-I
GMP Systems
Medro Systems
Meissner Filtration Products
Pall Corp
Phenomenex
Qosina
Steri Technologies

FILTERS, MICROFiltration
Avestin
Bopp USA
Chem Floxtronics
Chemical Transfer Partnership Corp
Eaton Technologies GmbH
Heinkel
Jaygo
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Pfautier
Steri Technologies

FILTERS, NUTSCHE
3V TECH USA
Bopp USA
Chem Floxtronics
Chemical Transfer Partnership Corp
Eaton Technologies GmbH
Heinkel
Jaygo
Kavon Filter Products Co
Pfautier
Steri Technologies

FILTERS, NYLON 66
Eaton Technologies GmbH
G-M-I
Kavon Filter Products Co
Pall Corp
Phenomenex
Qosina
Steri Technologies

FILTERS, POLYPROPYlene (GAS AND LIQUID)
Eaton Technologies GmbH
GMP Systems
Kavon Filter Products Co
Meissner Filtration Products
Pall Corp
Sartorius Stedin North America
Steri Technologies

FILTERS, PRESSURE
3V TECH USA
Avery Filter Co
Bopp USA
Buchiglas USA
Eaton Technologies GmbH
GMP Systems
Heinkel
Jaygo
Kavon Filter Products Co
Meissner Filtration Products
Pall Corp
Sartorius Stedin North America
Steri Technologies

FILTERS, PTFE (AIR AND LIQUID)
Bopp USA
Chem Floxtronics
GMP Systems
Kavon Filter Products Co
Meissner Filtration Products
Micropure Filtration

For vendor contact information, see Company Directory section.
For vendor contact information, see Company Directory section.
Terracon Corp
Scientific Industries
Walker Stainless
Union Scientific Corp
Servolift
Pope Scientific
Patterson Kelley
Neptune Chemical Pump Co
Myers Mixers
Meissner Filtration Products
Magna-Safe Intl
ROSS Mixers (Charles Ross & Son Company)
Scientific Industries
Servolift
Silverson Machines
Thomas Scientific
Union Scientific Corp
Walker Stainless
Equipment Co

ROSS Mixers (Charles Ross & Son Company)

Mixers, Vacuum
Admix
Briggs of Burton
Champion Trading Corp
EKATO Corp
EquiNet
Fristam Pumps USA
GEMCO
GMP Systems
Healthstar
Heinkel
Hondaosawa Micron Powder Systems
IAK Works
International Process Plants
IPP
Jaygo
JLS Intl
Keith Machinery Corp
Lee Industries
Magnase Safe Intl
ROSS Mixers (Charles Ross & Son Company)
Young Industries

Mixers, Powder
ACG North America LLC
Admix
Briggs of Burton
CapPlus Technologies
Champion Trading Corp
Coating Systems
De Dietrich Process Systems
DJS Enterprises
Dynamic Air
EKATO Corp
EquiNet
Fristam Pumps USA
GEMCO
GMP Systems
Healthstar
Heinkel
Hondaosawa Micron Powder Systems
IAK Works
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IPP
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Briggs of Burton
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Cleveland Eastern Mixers
Cytva
DCI
DCI-Biolatffe
De Dietrich Process Systems
EKATO Corp
Eppendorf
EquiNet
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Morse Mfg Co
Morsco
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Mixers, Vertical
3V Tech USA
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Chern Flontronics
DCI
DCI-Biolatffe
EKATO Corp
Ete/Alseop
Fristam Pumps USA
GEMCO
GMP Systems
Healthstar
Heinkel
Hondaosawa Micron Powder Systems
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Ross & Son Company
Schenck Process
Solvolt
Sigma Equipment Corp
Torpac
Uniion Scientific Corp
Whirlwind Engineering
Young Industries

Mixers, Self-Cleaning
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Alfa Laval Tank Equipment
BEEMatek Systems
Dynamic Air
EKATO Corp

Mixers, Vortexing
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GEMCO
Glove Scientific
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Healthstar
IPP
LC Dover
Jaygo
Kemutec
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Olsa USA
ROSS Mixers (Charles Ross & Son Company)
Young Industries

Moisture Control Systems
Goer
LT Industries
Monitor Technologies LLC
Munters Corp
Spirax Sarco
Thomas Scientific

Molds
Sigma Equipment Corp

Nitrogen-Enriched Air Generation
GMP Systems
Isolation Systems
Parker Hannifin
ProCepT

Nozzles
BEE Intl
BETE Fog Nozzle
GMP Systems
Kapa All Packaging Systems
Strahan Valves

O Rings
Dr Eichler Process Systems
Fenner Drives
G-M-i
GMP Systems
KMS Instruments
Qosina
Restek Corp
Sartorius Stedim North America
Sentinel Process Systems

Ovens, Drying
AWS Bio-Pharma Technologies
Buchler Corp
Bahler Aeroglide
Champion Trading Corp
Despatch - ITW EAE
DJS Enterprises
EquiNet
Federal Equipment Co
Grieve
Gruenberg
Healthstar
Hosokawa Micron Powder Systems
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Kemutec
Key Intl
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Morse Mfg Co
Morsco
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Nicos Group
Olsa USA
Readco Kurimoto LLC
ROSS Mixers (Charles Ross & Son Company)
Young Industries

Ovens, Revolving
EquiNet
Verder Scientific

Ovens, Sterilizing
AWS Bio-Pharma Technologies
Bahler Aeroglide
Despatch - ITW EAE
EquiNet
ESCO Technologies
Federal Equipment Co
Grieve
Gruenberg
Healthstar
Nicos Group
Optima Machinery Corp
Pink GmbH Thermosysteme
Remers Electra Steam
Thomas Scientific

Ovens, Vacuum
EquiNet
F.P.S. Food and Pharma Systems srl
Federal Equipment Co
Grieve
Healthstar
Olsa USA
PHC Europe B.V.
Pink GmbH Thermosysteme
Thomas Scientific
Verder Scientific

Pans, Coating
AC Compacting LLC
DJS Enterprises
Dram USA
EquiNet
Federal Equipment Co
Freud-Vector Corporation
Healthstar
IMA S.p.A.
International Process Plants
IPP
Keith Machinery Corp
Nicos Group
ProCepT
Thomas Processing

Pans, Polishing
Dram USA
EquiNet
Federal Equipment Co
Healthstar
Keith Machinery Corp
Nicos Group
ProCepT

Pasteurizers
API Heat Transfer
Feldmeier Equipment
Koch Machinery Corp
MicroThermics
Pick Heaters

Pelletizers
Federal Equipment Co
International Process Plants
IPP
Keith Machinery Corp
Nicos Group
Sidel
Sigma Equipment Corp

Photometers
Air Techniques Intl (ATI)
Artem Epeendorf
First Sensor
Konica Minolta Sensing Americas
NUCON Intl
Optic-Danulat
Thomas Scientific
SOP DEVELOPMENT (SEE ALSO INFORMATION TECHNOLOGIES SECTION)  
I Holland Ltd  
QualityHub  
Siemens  

SPARGERS  
Chem Flowtronics  
Cytiva  
Mott Corp  
PickHeaters  
Schulte & Koerting  

SPHERONIZATION MACHINERY  
AC Compacting LLC  
ArmiField Ltd  
Fluid Air  
Kollme-Sanderson ProCepT  

SPRAY NOZZLES  
Arcon Industries  
BUCHI Corp  
EquiNet ESC  
Federal Equipment Co  
Fluid Air  
gr�ner USA L.L.C  
HealthStar  
Isolation Systems  
IVEK Corp  
Rubber Fab  
Sonicas & Materials  
Strahan Valves  

STATISTICAL ANALYSIS (SEE ALSO INFORMATION TECHNOLOGIES SECTION)  
FILTec  
Minitab  

STERILANTS, LIQUID  
Cloridrys Solutions  
DevCo Labs  
Steris Corp  
Thomas Scientific  

STERILE AIR FILTERS  
Dominic microBAN  
Isolation Systems  
Meissner Filtration Products  
Microperite Filtration  
Pall Corp.  
Thomas Scientific  

STERILE STORAGE UNITS  
Hurt Corp  
Isolation Systems  
Metro - InterMetro Industries Corp  
Ruland Engineering & Consulting GmbH  
Thermo Fisher Scientific  
Thomas Scientific  
Optima Machinery Corp  
Steris Corp  
Optima Machinery Corp  
Steris Corp  

STERILIZERS, IONIZING RADIATION  
EquipNet  
Molded Fiber Glass Tray Co  
Optima Machinery Corp  
Steris Corp  

STERILIZERS, MEMBRANE FILTRATION  
3M Co  
EquipNet  
Meissner Filtration Products  
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STERILIZERS, OZONE GENERATION  
EquipNet  
Xylem Services GmbH  

STERILIZERS, SUBMICRON  
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STERILIZER CONTROLS, AUTOCLAVE  
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UTM USA  

STERILIZERS, AUTOCLAVE  
AWS Bio-Pharma Technologies  
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Carflex  
Consolidated Sterilizer Systems  
EquipNet  
ESCO Technologies  
ETC  
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HealthStar  
Keith Machinery Corp  
Kinematica  
Molded Fiber Glass Tray Co  
Nicos Group  
Steris Corp  
Thomas Scientific  
Tuttunauer USA Co Ltd  

STERILIZERS, DRY HEAT, ELECTRIC  
Central Research Labs (CRL)  
Despatch - ITW EAE  
EquipNet  
Federal Equipment Co  
Gruen  
Inotech BioScience LLC  
Nicos Group  
Optima Machinery Corp  
Pink GmbH Thermostyme  
Thomas Scientific  

STERILIZERS, DRY HEAT, GAS  
Despatch - ITW EAE  
EquipNet  
ETC  
Nicos Group  
Optima Machinery Corp  
Thomas Scientific  

STERILIZERS, GAS (CHLORINE OXIDE)  
Bonal Plastics  
Cloridrys Solutions  
EquipNet  

STERILIZERS, GAS (ETO)  
Cloridrys Solutions  
EquipNet  
ETC  
Gelige USA  
Molded Fiber Glass Tray Co  
Nicos Group  

STERILIZING TUNNELS  
AWS Bio-Pharma Technologies  
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Coozial Machine Co  
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F.P.S. Food and Pharma Systems srl  
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HealthStar  
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ParTech Machinery Corp  
Romac North American  
Shibuys Hoppmann Corp  
Syntegon Pharma Technology  

STILLS  
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Stirling Corp  
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Globe Scientific  
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Keith Machinery Corp  
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Magna-Safe Intl  
Omni Intl  

STOPDOCKS  
Boral Plastics  
Thomas Scientific  

STOPPER HANDLING EQUIPMENT  
Capmatic Ltd  
Coozial Machine Co  
Gelige USA  
gr�ner USA L.L.C  
HealthStar  
METO SYSTEMS  
Pharmasystems  
Reiss Mfg  
Servo-It  
Shibuys Hoppmann Corp  

STORAGE EQUIPMENT  
AngstoMix  
Custom Powder Systems  
CustomVault  
Cyntiva  
Globe Scientific  
HEMCO Corporation  
I Holland Ltd  
Isolation Systems  
Jenike & Johanson  
Justrite  
Lista Intl Corp  
Metro - InterMetro Industries Corp  
Molded Fiber Glass Tray Co  
Natoil Engineering  
Parameter Generation & Control  
Remcon Plastics  
ROSS Mixers (Charles Ross & Son Company)  
Servo-It  
Snyder Industries  
Tamper Technologies Ltd  
Walker Stainless Equipment Co  

STRAINERS  
Fieldmeier Equipment  
GMP Systems  
Russell Finex  
Thomas Scientific  
Umbloc-Pump  

SUPPLY CHAIN MANAGEMENT (SEE ALSO INFORMATION TECHNOLOGIES SECTION)  
Deacom  
INTELL group  
Qosina  
Tunnel Consulting  
VAI (Vormittag Associa)  

SUPPOSITORY MACHINES  
DJS Enterprises  
KeyTec  

corporate  

SUPPOSITORY TESTERS  
Texture Technologies Corp  

TABLES, STAINLESS  
Advance Tabco  
Atmos-Tech Industries  
Blue Thunder Technologies  
CapPlus Technologies  
EquipNet  
Federal Equipment Co  
GMP Systems  
HealthStar  
Integrated Packaging Systems  
Liberty Industries  
LM Air Technology  
Mendel Co  
Metro - InterMetro Industries Corp  
ProMach  
Thomas Scientific  

TABLET DEDUSTERS  
AC Compacting LLC  

TABLET FILLING AND COUNTING MACHINES  
Capmatic Ltd  
Champion Trading Corp  
DJS Enterprises  
EquipNet  
Federal Equipment Co  
HealthStar  
IMA S.p.A.  
Intelligent Pharmaceutical Technologies Ltd  
Integrated Packaging Systems  
Keith Machinery Corp  
Key Inti  
Kirby Lester  
Mendel Co  
Modular Packaging Systems  
R. W. Hartnett Co  

TABLE HANDLING EQUIPMENT  
AC Compacting LLC  
Ackley Machine Corp  
Custom Powder Systems  
Efficient Automated Machine Corp  
EHS Solutions LLC  
EquipNet  
Eriez  
Federal Equipment Co  
Fette Compacting America  
HealthStar  
IMA S.p.A.  
Jenike & Johanson  
Key Inti  
Kirby Lester  
Kraemer US LLC  
LB Bohle LLC  
Mendel Co  
METO SYSTEMS  
Molded Fiber Glass Tray Co  
Natoil Engineering  
Packaging Machines  
Pibb  
R. W. Hartnett Co  
Remcon Plastics  
Servo-It  
Systex  
Tamper Technologies Ltd  
Wilson Tool Intl  

TABLET HOPPERS  
Champion Trading Corp  
Custom Powder Systems  
Elizabeth Companies  
EquipNet  
Eriez  
Federal Equipment Co  
Fette Compacting America  
HealthStar  
IMA S.p.A.  
Integrated Containment Systems LLC  
Integrated Packaging Systems  
Jenike & Johanson  
Keith Machinery Corp  
LB Bohle LLC  
Mendel Co  
Nicos Group  
Palace Packaging Machines  
R. W. Hartnett Co  
Remcon Plastics  
Servo-It  

TABLET PRINTING EQUIPMENT  
AC Compacting LLC  
Ackley Machine Corp  
Boral Plastics  
De Dietrich Process Systems  
EquipNet  
Eriez  
Federal Equipment Co  
Fette Compacting America  
HealthStar  
IMA S.p.A.  
Keith Machinery Corp  
Key Inti  
KIRKUSA USA  
KORSCH America  
Kraemer US LLC  
Mendel Co  
Natoil Engineering  
Sancillo & Co  
Smi  
Vac-U-Max  

For vendor contact information, see Company Directory section.
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Designed to be integrated by press fit or heat sealing into fluid delivery bags

◊ Eliminates the use of needles and spikes
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◊ Eliminates leaking and dripping when disconnected
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### Table: Buyers' Guide 2021

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<th>Company Name</th>
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HEMCO Corporation
Hutches & Hutchins
ISO Tech Design
Isolation Systems
ITW Texwipe
JM Coull
Laminar Flow
Liberty Industries
LM Air Technology
Nichos Group

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Atmos-Tech Industries
Clean Caps
Clean Powder Systems
Ecolabs
ESCO Technologies
Extract Technology
F.P.S.
Food and Pharma Systems srl
Germfree
Genting USA
Integrateed Containment Systems LLC
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Siemens
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- Federal Equipment Co
- FP Developments
- Garvey Corp
- groninger USA L.L.C
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- IMA S.p.A.
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- Keith Machinery Corp
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- Nedco Conveyor Technology
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### ALUMINUM SEALS
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- Comar
- Constantia Flexible Packaging
- J.G. Finneran Associates
- Kaps-All Packaging Systems
- Optima Machinery Corp
- Tamper Technologies Ltd
- Tekni-Plex
- West Pharmaceutical Services

### AMPUL FILLING EQUIPMENT
- ATs Automation
- Bausch+Stroebel
- Chemical Machine Co
- Capsules Intl
- E. P. Johnson
- Federal Equipment Co
- HealthStar

### AMPUL PACKING EQUIPMENT
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- Chemical Machine Co
- Federal Equipment Co
- HealthStar

### AMPUL SEALING EQUIPMENT
- Auto-Mate Technologies LLC
- Bausch+Stroebel
- Chemical Machine Co
- Federal Equipment Co

### ANTI-COUNTERFEITING
- Hong-Nwee
- Natoli Engineering

### ASEPIC FILLING EQUIPMENT, LIQUID
- ASEPIC FILLING EQUIPMENT
- Bausch+Stroebel
- Chemical Machine Co
- ESCO Technologies
- Federal Equipment Co

### BAR CODE LABELS
- enLabel Global Services
- FILTEC
- OK Sealer
- SSE Technologies
- Veletak Associates

### BAR CODE PRINTING EQUIPMENT
- Bell-Mark
- Clear Micro Systems
- Dalemak Industries
- FILTEC
- Fujitsu Components
- Gem Marking Coding
- Greydon
- Griffin-Rutgers Co
- Iconotech
- Key Intl
- Matthews Intl Corp
- OK Sealer
- SSE Technologies
- WIPOTEC-OCS

### BAR CODE SYSTEMS
- Dalemark Industries
- EquipNet
- FILTEC
- Greydon
- HD Barcode LLC
- Kaps-All Packaging Systems
- SSE Technologies
- Veletak Associates
- WIPOTEC-OCS

### BAGS, BAG-IN-BOX
- Black Forest Container Systems
- Bossar USA
- F.P.S. Food and Pharma Systems
- FILTEC
- Glendyne
- ILC Dover
- Kaps-All Packaging Systems
- OPTIMA pharma GmbH
- Optima Machinery Corp
- Per-Fil Industries
- Tamper Technologies Ltd
- Vibra Screw

### BAGS, FILM-LINED
- ILC Dover
- KNP Corp
- Lonza
- Meissner Filtration Products
- OK Sealer
- Tamper Technologies Ltd
- Transcendia

### BANDERS
- HealthStar

### BANDS, ADHESIVES, BAGS, BAG-IN-BOX
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- Bag executives
- Chemicals
- E. P. Johnson
- Kaps-All Packaging Systems
- Optima Machinery Corp
- Tamper Technologies Ltd

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- OK Sealer
- Tamper Technologies Ltd
- Transcendia

### BANDERS
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**CAP SEALERS, INNER SEAL**

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**CARTONING SYSTEMS**

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TechResearch
VWR Intl LLC
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Milestone
Perkin Elmer Corp
Thomas Scientific

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CEM Corp
CW Brabender Instruments
Hiden Analytical
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LT Industries
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Monitor Technologies LLC
Omega Engineering
Sartorius Stedim North America
Surface Measurement Systems Ltd NA
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VWR Intl LLC

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Hiden Analytical
LECO Corp
Lighthouse Instruments LLC
Mettler-Toledo
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Malvern Instruments
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Formulacon
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Verder Scientific
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CEM Corp
HORIBA SCIENTIFIC
Hотoki-Danulat
JASCO
Kusam Hormone
Mettler-Toledo
Nalge Nunc
Perkin Elmer Corp
Qosina
Schwarz Microscopische Instrumentenfabriek
TDK-Lambda
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PHOTOSTABILITY TEST CHAMBERS
Atlas Material Testing Technology LLC
Gigahertz-Optik
Parameter Generation & Control
Powers Scientific
Weiss Technik North America - CSZ Products

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Eppendorf
Globe Scientific
Metter-Toledo
Perkin Elmer Corp
Qosina
VWR Intl LLC

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Artel
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Bel-Art SP Scienceware
BioTek
Cadence Science
Corning
Eppendorf
Fluid Metering
Globe Scientific
Hamilton Co
IVEX Corp
Metter-Toledo
Oyster Bay Pump Works
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Zinser NA

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Eppendorf
Metter-Toledo
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POLARIMETERS, AUTOMATIC
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ATAGO USA
Jasco
VWR Intl LLC

POLYMER ANALYZERS
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Extrel CMS
LT Industries
Metrohm Group USA
Microtrac
Wyatt Technology

POWER FLOWABILITY
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Hosokawa Micron Powder Systems
Jenike & Johanson
Monitor Technologies LLC
Natoli Engineering
Surface Measurement Systems Ltd NA
Teknai Technologies Corp
Vac-U-Max

POWER TESTING/TESTER
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CEM Corp
Copley Scientific Ltd
Hosokawa Micron Powder Systems
Jenike & Johanson
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- Dry Heat Sterilization
- Depyrogenation
- Water For Injection (WFI) Rinsing

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- RTU Vials, Assembled (Depyrogenated & Sterile Vials Assembled With Stopper And Seal)
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Thermo Scientific
VWR Intl LLC

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Eppendorf
Huntington Lab
Konica Minolta Sensing Americas
Perkin Elmer Corp
Thomas Scientific
VWR Intl LLC

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First Sensor
JASCO
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Thermo Fisher Scientific
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Ametek Process Instruments
Bruker
Eppendorf
First Sensor
IET | Intl Equipment Trading Ltd
JASCO
Metrohm USA
Optometrics Corp
Perkin Elmer Corp
Shimadzu Scientific Instruments
Thermo Fisher Scientific
VWR Intl LLC

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Eppendorf
First Sensor
IET | Intl Equipment Trading Ltd
JASCO
LT Industries
Metrohm USA
Molinex Corp
Optometrics Corp
Perkin Elmer Corp
Shimadzu Scientific Instruments
Thermo Fisher Scientific
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Eppendorf
First Sensor
JASCO
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Bruker
First Sensor
HORIBA SCIENTIFIC
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JASCO
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Rigaku Americas Corporation
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Eppendorf
First Sensor
HORIBA SCIENTIFIC
IET | Intl Equipment Trading Ltd
JASCO
Konica Minolta Sensing Americas
Metrohm USA
Metler-Toledo
Optometrics Corp
Perkin Elmer Corp
Shimadzu Scientific Instruments
Thermo Fisher Scientific
VWR Intl LLC

SPECTROPHOTOMETERS, UV
Ametek Technologies
Optometrics Corp
Perkin Elmer Corp
Shimadzu Scientific Instruments
Thermo Fisher Scientific
VWR Intl LLC

STABILITY TEST CHAMBERS
Atlas Material Testing Technology LLC
ETC
Formulation
Isolation Systems
Parameter Generation & Control
Powers Scientific
Thomas Scientific
Weiss Technik North America
- CSZ Products

STANDARDS, PARTICLE SIZE AND COUNTER
Bangs Labs
Biotest Diagnostics Corp
Blue Thunder Technologies
MilliporeSigma
Particle Measuring Systems
Thomas Scientific
VWR Intl LLC

STEAM GENERATORS
AWS Bio-Pharma Technologies
Dristeam
Getinge USA
Isolation Systems

STEAM QUALITY TESTING EQUIPMENT
Cartex

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VWR Intl LLC

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Hutchins & Hutchins
Isolation Systems
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JAF Consulting
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LT Industries
Mar-Kov Computer Systems
MasterControl
Metrohm USA
Metlin-Toledo
Nato1 Engineering
NNE Pharmaplan
Particle Measuring Systems
PCI:
Pharmaceutical Calibrations And Instrumentation
Perkin Elmer Corp
PharmaDirections
PharmaSys
Prime Technologies
ProcessPro Software
Qpharm
QualityHub
R. Kraft
RCM Technologies
Rees Scientific
Sensitec
Siemens
Sparta Systems
Texto
Texture Technologies
CQO
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ValiMation
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Automated Control Concepts
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Bridge Associates Int'l
CustomVault
E Instruments Int'l
ENV Services
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InfinityQS Int'l
Nato1 Engineering
NNE Pharmaplan
Perigen Int'l
RCM Technologies
Rees Scientific
Sensitec
Siemens

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Automated Control Concepts
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Clarkston Consulting
Complete Inspection Systems
Court Square Group
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enLabel Global Services
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LT Industries
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Particle Measuring Systems
PCI:
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PharmaDirections
PharmaSys
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ProcessPro Software
Qpharm
QualityHub
R. Kraft
RCM Technologies
Rees Scientific
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Siemens
Sparta Systems
Texto
Texture Technologies
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CSoles
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Complete Inspection Systems
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FP Developments
FSI Technologies
GEA Process Engineering
Getinge USA
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IPS-Integrated Project Services LLC
MasterControl
NNE Pharmaplan
Perigen Int'l
Prior Scientific
ProcessPro Software
RCM Technologies
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Sparta Systems
SPEC Process Engineering & Construction
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CIMINFO Software
Clear Automation
EAM
Festo Corp
FP Developments
FSI Technologies
GEA Process Engineering

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NNE Pharmaplan
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ProMach
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Much of our business is driven by our clients coming back with each new venture and telling their friends. We put the right people in the room to get the project done right. We are a true partner that works side-by-side with the client.

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2021
Buyers’ Guide Case Studies

This year’s *Buyers’ Guide* features the following case studies, which highlight a variety of industry topics.

**CASE STUDIES**

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AIZON HELPS LEADING BIOTECH COMPANY USE AI TO IMPROVE YIELD

A leading biotech company outsourced much of their data analysis to data scientists and analysts from a well-known consulting firm. Things seemed to be going well, but the analysts and the horizontal data analytics solution they were using lacked contextual awareness into manufacturing processes. Knowing that process knowledge would help further manufacturing operations, the company’s leadership decided the company needed additional help.

The company reached out to Aizon, which has an enterprise SaaS data and AI platform specifically designed and optimized to support GMP activities for leading life sciences organizations. Specifically for this case study, Aizon was called in to identify how artificial intelligence (AI) could be used to further optimize yield. Aizon transforms manufacturing operations leveraging data from multiple sources to power advanced analytics and other smart factory technologies. Thinking big, the biotech company tasked Aizon with analyzing the centrifugation step, which is where the harvesting process starts once fermentation is completed in the bioreactor. Average yield was already tracking at an impressive level. Improving on that baseline would be difficult, but immensely valuable.

The Aizon AI Consulting Services team introduced their unique methodology to the company’s operations team. The integrated team would be able to identify real opportunities to leverage AI in their specific environment and build a roadmap to achieve those goals. Out of five areas identified where AI could have immediate impact, yield optimization in the centrifugation process was selected as the most beneficial, but also one of the most difficult to see benefits.

Aizon then implemented the Aizon GxP AI Platform to analyze the centrifugation process and make actionable recommendations. In just under six weeks, Aizon was able to use its manufacturing process expertise, data analytics and AI capabilities to put the centrifugation step in the context of other upstream and downstream processes. This provided stakeholders with deep insights into what happens to yield in this critical step in the process; The Aizon Platform was configured to discover which parameters most affected the yield in the centrifugation process and how to finely tune it.

The team was able to analyze five years of historical batch data to discover a direct correlation between hold up volume and time between process operations. It was determined that using this analysis to vary how much time should lapse between these processes for each batch would save an appreciable amount of product, resulting in millions of dollars in recovered revenue.

ABOUT AUTHOR
Lawrence is responsible for the delivery of solutions that increase the efficiency and effectiveness of our customers’ critical business processes and that provide performance insights.

ABOUT THE COMPANY
Aizon is an AI software provider that transforms manufacturing operations in highly regulated industries using advanced analytics, artificial intelligence, and other smart factory technologies.

Company Name: Aizon
Company Phone: +1 628.243.2513
Company Email: hi@aizon.ai
Company Website: https://aizon.ai
**NEED TO MOVE FAST? START WITH A TABLET**

Pharmaceutical companies both large and small have a compelling need to bring new drug candidates into the clinic quickly. Their management teams demand it, their investors expect it, and most importantly the patients they serve require it. To address this ‘speed to clinic’ challenge, most companies take a shortcut approach to their drug products using neat API in a suitable container. The problem with these traditional approaches is that they do not plan for long-term success—process scale-up and commercial manufacturing cost of goods often become issues later in the development process, resulting in reformulation work. This adds cost, risk, and time to the overall development plan. CoreRx has successfully deployed an innovative approach to drug product development that enables both speed to clinic AND speed to market, which we describe in the following case study.

A NCE drug candidate was entering phase 1 clinical studies, and the associated timeline for clinical supply was so aggressive that a simple, more traditional approach using drug-in-bottle for reconstitution initially appeared best. However, the project plan did not account for later dosage form development or subsequent BE/BA bridging studies. After consideration of the broader timeline, we decided jointly with our partner to pursue a tablet formulation from the outset.

A traditional formulation and process development project for a solid oral dosage form typically starts with pre-formulation studies to characterize the API before moving to excipient compatibility studies, generating prototypes, and establishing lead and back-up formulations. These initial development milestones generally take at least 2-3 months to complete, but in this case that was too much time.

Instead, the CoreRx formulation team used their expertise and focused on key API attributes (chemical and physical stability of the API, and form changes), together with compressibility, wettability and processability. With this in mind, the team immediately devised a simplified QbD approach with small batches of prototypes that contained common, low risk excipients. This meant deferring excipient compatibility studies until later. The team also selected a dry granulation method of manufacture to improve powder flow properties and ensure acceptable content uniformity. In parallel, the analytical team started method development and validation activities.

This approach achieved first patient dosing in under 8 months. Moreover, by pursuing a commercially viable process and product from the outset, CoreRx estimated an overall time savings for the program of up to 6 months.

**ABOUT CoreRx**

CoreRx is an industry leading CDMO offering drug product services, including formulation development, clinical manufacturing, and commercial supply of solid, liquid, and topical dosage forms.
EMBRACING AGILE METHODOLOGY FOR E&L EXCELLENCE

Extractables and leachables (E&L) studies traditionally take on a linear, sequential process, in the form of a waterfall project, where each phase is inflexible and dependent on its predecessor. A number of these project phases involve technically challenging analytical work and toxicological risk assessments, which offer an array of challenges for timeline management for a contract research laboratory in collaboration with the project stakeholder. In general, the waterfall project management approach for an E&L study leaves little to be performed in parallel, and a large proportion of tasks reside along its critical path. When faced with looming deadlines, waterfall-type projects only offer two options; start earlier or deliver late. Neither option aligns with the contract lab’s capacity nor project sponsor’s need for a supported leachable study prior to regulatory submission. In order to close this gap, we look to the software development industry to employ key aspects of the Agile product management methodologies.

Agile product development is a philosophy at the center of leading software companies and is an incremental, iterative approach based on continuous feedback. Rather than in-depth planning, the Agile development principles promote working product functionality over comprehensive documentation. At first glance, an approach that de-prioritizes documentation is simply incompatible with a highly regulated environment such as the pharmaceutical industry. However, this methodology can be particularly useful to the phases pertinent to research and development (Figure 1).

When the focus is set on building an Agile product team of empowered members, testing laboratories can implement Agile methodologies into their operations for delivery of a robust E&L program. Phase III of the E&L project (analytical method development and validation) most closely represents the software development process in the tech industry. In a conventional waterfall project management approach, the requirements gathering is dependent on completion of Phases I & II. Since analytical method development can face unforeseen technical challenges, it has the highest risk of delaying the overall delivery of the leachable study. Applying an Agile development approach can gain valuable time by leveraging SME knowledge early in the E&L project to begin Phase III before the completion of Phases I & II.

There are still elements of an E&L program that must occur in a waterfall fashion under strict documented and quality controls. However, this hybrid approach to E&L project management increases the likelihood of successful delivery of a leachable study in time for regulatory submission and gives our customers “The Element Advantage”.

REFERENCES
THE FINANCIAL BENEFITS OF OFF-SITE PREFABRICATED CLEANROOM INFRASTRUCTURES

The paper analyzes the financial benefits of off-site, prefabricated cleanroom infrastructures to traditionally on-site built. It discusses the total cost of ownership of an example 4 x 2,000L monoclonal antibody site.

Traditional cleanroom infrastructures, gypsum, or monolithic wall panels have been utilized over the past with varying levels of success. One of the most often proclaimed benefits are the costs of on-site built projects. Characteristically, the cost quoted at the beginning of a construction project seems to be attractive, but construction estimates are typically +/- 50% at feasibility (pre-Concept) and +/- 25% at end of Conceptual Design. Given the above accuracy ranges, industry surveys establish that such cost proposals are inaccurate in most cases (Aspen, 2019, Sinclair, 2021). These types of cost control variations cause major problems in budgeting for and funding projects, as the funding value is either inflated to allow for cost variation with the risk that future funding will not be approved, or another round of funding is needed mid-project. Both are undesirable scenarios.

Off-site prefabricated cleanrooms allow for robust cost budgeting, as the resource and material load are well defined and known. The accuracy of the estimated cost of the project is much better than traditional built and usually the initial cost quoted is held. This makes the funding approach much more realistic and reliable.

Moreover, the reliability of the delivery time and speed of construction are also superior. These factors have a tremendous impact on capacity planning, upfront investment needs and incremental value. The faster the site is built, the faster product batches are produced, which can provide significant benefits to an organization. Traditional construction happens on-site, which requires sequential steps with longer overall time-to-run and very low flexibility of any time compensation if the project falls behind, for example due to delays of material supplies or weather-related issues. In a recent Aspen survey, 68% of the participants expressed that the timelines are typically not fulfilled, and the remainder stated the timeline is “usually” kept.

In off-site prefabrication the timelines are met, as the construction happens in a controlled environment, with a consistent and experienced workforce and if a timeline drifts, overtime can be employed to compensate for such drift. The entire end-user facility is established much faster as the construction project runs parallel; the shell building, utilities, cleanroom infrastructure and equipment are all built parallel, and the site can be established in half the time a traditional site is build.

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ABOUT THE AUTHOR
Maik Jornitz is the CEO of G-CON Manufacturing Inc. He is a 35-year veteran of the biopharmaceutical industry with expertise in biopharmaceutical processes and facilities.

ABOUT THE COMPANY
G-CON Manufacturing is the global leader in the design, construction, qualification, and installation of off-site, prefabricated cleanroom units called PODs, with focus of serving the biopharmaceutical industry.
BUILD CUSTOM PRODUCTS WITH THE RIGHT PARTNER

The choice to manufacture a custom product involves risk that can only be mitigated by choosing the right partner. At Halkey-Roberts, we always first try to find an off-the-shelf solution, but we know the trade-offs. Our experience has taught us when and how to move to a custom solution. Custom products now account for approximately 20% of our business. Work that crosses all product lines and markets.

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The process to design and build a custom product with Halkey-Roberts starts with an assessment of your application and design requirements. Once we know we have the manufacturing capability, we will move to a more detailed review. This involves a thorough information exchange regarding timing and costs. The resulting agreement covering design, development, and production ensures a final product solution delivered in a highly cost-effective manner for both parties.

The cost of custom development is driven by multiple factors. To best manage them, it helps that we are flexible. We start with a broad array of proven products and can offer mass customization, i.e. small tweaks to off-the-shelf items.

When fully custom, we are able to work at small volume levels so you can better manage your commitment. We incorporate our manufacturing technology into your product development to provide the best solution and a cost-effective one for both partners.

We helped a global pharmaceutical company develop a custom valve solution for their home-use infusion system. We were able to integrate our existing technology into a custom product that improved the user experience at a reasonable product cost.

The ability to provide mass customization to our customers is our secret weapon. We combine your idea with our in-depth product knowledge and expertise in flexible automation to provide a custom product at a low unit production cost. This helps our customers differentiate their end products and provide their clients with truly custom solutions. For many, mass customization is simply not possible. For Halkey-Roberts, we do it day in, day out.

ABOUT STEVE BELLO
Steve Bello is the VP of business development and has been with Halkey Roberts for over 22 years.

ABOUT HALKEY ROBERTS
Our history dates back 80 years as a supplier to the Medical and life saving OEM market.
TUMBLER BLENDING CASE STUDY: MINIATURIZED NEAR INFRARED SPECTROSCOPY APPLIED FOR A NON-DESTRUCTIVE UNIFORMITY AND QUANTIFICATION MONITORING OF MAGNESIUM STEARATE

In all the manufacturing fields of oral solid dosage forms, powder blending represents a critical step for ensuring the blend uniformity of the final product. The raw material particle properties, blender geometry, blending time, filling and rotation speed are the main factors to consider for achieving the optimal blending process efficiency. Besides other compounds, which comprise the final formulation, lubricants are essential to ensure the success of the manufacturing since many failures are caused by issues related to lubrication.

Albeit a fairly small amount is used (0.25%-5.0% w/w), lubricants play important roles because they can act in three roles as an excipient: true lubricant, anti-adherent or glidant. As a true lubricant, it reduces the friction between the solid product and the metallic machine surfaces. As an anti-adherent, the lubricant reduces the formulation’s stickiness, which also decreases friction.

Lubricants can also function as glidants, reducing interparticle friction in the formulation. A glidant typically forms layers between particle surfaces or at their interfaces and increases the distance between the particles to improve flowability. They consist of long-chain molecules with active end groups, which allows them to be readily adsorbed on the surfaces of particles to form a film, creating boundary lubrication.

In this work, according to the FDA’s guideline, which encourages the implementation of process analytical technology (PAT) for processing, a miniaturized near infrared spectrometer was applied to monitoring blending of a binary lactose-based placebo mixtures lubricated with magnesium stearate, that probably is the most commonly used excipient as lubricant. The aim was to investigate both uniformity and quantification of such lubricant during a process blending performed in a tumble blender. A preliminary calibration-free, qualitative method (Moving Block Standard Deviation) was used to determine the endpoint, which was afterwards modelled by a quantitative approach (Partial Least Squares).

EXPERIMENTAL PART

INVESTIGATION OF BLENDING UNIFORMITY END-POINT.

A total of six experimental trials were carried out by using a placebo formulation based on lactose monohydrate (Foremost® NF Lactose 312, USA) lubricated with magnesium stearate (Brenntag, Italy). The mixtures (Table 1) were blended in a tumble blender (Cyclops Lab, IMA), a laboratory scale bin blender equipped with a 15 L bin, which features a maximum filling of 70% of the full container capacity and an adjustable rotational speed between 4 and 20 RPM. The starting batch size was selected according to the lactose monohydrate bulk density of 0.497 g/ml corresponding to the maximum bin filling. Magnesium stearate was added to the lactose monohydrate by varying the amount from 0.25% up to 5%. Powders were blended by rotating the bin at 10 RPM for 5 minutes by monitoring the lubricant distribution over the time to define the blending end-point.

The MicroNIR™ (PAT-W, Viavi, USA) was employed to wirelessly acquire real-time the diffuse reflectance spectra in the wavelength range of 908–1676 nm.

Table I. Blend formulation: lactose (95%-99.75% w/w) and magnesium stearate (0.25%-5.0% w/w).

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Thanks to its small size and robustness, the sensor is clamped on the lid of the bin through a dedicated sight-glass flange; its core technology is the novel thin-film linear variable filter (LVF) used as the dispersive element. The absence of moving parts, the compact optical design and light weight of the MicroNIR allow constant speed rotation (no acceleration / deceleration due to unbalanced weight) small footprint of blender protective shield, if necessary, as well as long term stability, with no need for frequent recalibration.

The data processing was performed applying the Moving Block Standard Deviation (MBSD), a qualitative analysis approach that calculates the standard deviation of the acquired spectra across the entire spectral region. MBSD belongs to the family of the calibration-free, unsupervised methods and allows to monitoring the process with no need for prior knowledge of NIR spectra of the analysed matrix, its pure ingredients or relative concentrations. The MBSD approach allows to evaluating the spectral variability in the data set, which provides an indirect measure of uniformity. The trajectory of the MBSD tends to a constant value when the blend gets to be toward homogeneity, which greatly helps identifying the process blending endpoint.

**Figure 1.** Moving Block Standard Deviation trajectory

In accordance to the results obtained by the MBSD approach, a quantitative model was developed considering the average spectrum of the last 15 signals for each of the six trials. The average data were processed by means of two different mathematical transformations such as Standard Normal Variate (SNV) and first derivative.

Data pre-treatment is a typical preliminary step of near infrared analysis, which highlights the correlation between spectral information and the species of interest (**Figure 2**).
Afterwards, Partial Least Squares (PLS) was applied to the transformed spectra. With no need to specify the region of interest, PLS automatically calculates the correlation between the spectral variance in the data set and the concentration values, resulting in a plot of actual concentration values versus calculated, as well as calibration error.

The Predicted vs Reference plot compares reference (x-axis) and predicted (y-axis) concentration values of magnesium stearate of both, in calibration (blue dots) and in cross validation (red dots) spectra.

The predicted vs. reference plot (Figure 3) straight line indicates the perfect (i.e.: theoretical) correlation between predicted and measured values, while the dots represent the distance to such ideal correlation of each calibration and validation sample; the closer is the slope to 1, intercept to 0 and correlation (R2) to 1, the higher the robustness of the model.

In particular, the obtained values of root mean square error (RMSE) in cross validations (0.12 with “Leave-one-out”) and R-Square (0.99) show the stability and the reproducibility of the mathematical PLS model.

CONCLUSIONS

In conclusion, MicroNIR sensor turned out to be a very powerful tool to determine the process blending end-point and magnesium stearate content uniformity by using a two-compounds placebo lactose-based formulation.

Moving Block Standard Deviation allows to identifying the optimal process conditions for an efficient and successful blending in Cyclops tumble blender while the development of a PLS model can be applied at-line for the low-dosed lubricant quantitative determination.

REFERENCES


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ABOUT THE AUTHOR

Kevin McMurtrie is the Global Business Manager for VAI’s Documentation, Transfer Systems, and RFID Tracking Solutions division.

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