

VOLUME 10 — 14 INDEX

Side bar body - Information such as who to contact, etc.

Affinity Ligands

See *Analytical Techniques*.

Analytical Techniques

- Spectroscopic Determination of Chelator Content in Antibody-Chelator Conjugates: UV-Vis, Fluorescence, and MALDI-TOF MS Studies. E. Dadachova. November 2000, 40-44.
- Intentionally Degrading Protein Pharmaceuticals to Validate Stability-Indicating Analytical Methods. J. Yu. November 2000, 46-50.
- Improving the ESD Procedure for Outlier Testing. M.A. Djauhari. March 2001, 42-46.
- Demonstrating Product Comparability. H.K.B. Simmerman. September 2000, 58-62.
- The Evolving Role of Product Characterization During Development. J. Faulkner. June 2000, 26-34.
- Differential Scanning Calorimetry: A Practical Tool for Elucidating Stability of Liquid Biopharmaceuticals. R.L. Remmele, Jr. and W.R. Gombotz. June 2000, 36-46.
- Detecting and Removing Porcine Viruses: To Prevent Contamination of Biopharmaceutical Raw Materials. B.J. Potts and W.J. Kivens. May 2000, 26-31.
- Using Molecular Beacons to Quantify Low Levels of Type I Endonuclease Activity. R.J. Strouse et al.. April 2000, 40-47.
- Detecting PEG-rHu MGDF in Rhesus Monkey Serum: An Enzyme-Linked Immunosorbent Assay. D. Chen et al.. April 2000, 48-50.
- Validation of a Chemiluminescent Hybridization Assay for Quantitative Determination of Host Cell DNA in Clarified Conditioned Medium. B. DiPaolo X. Ji, and K. Venkat. May 1999, 38-48.
- Technical Note: An Exact Test for Outlier Detection. M.A. Djauhari. June 1999, 56-59.
- Preparation and Qualification of Certified Reference Materials and Working Standards. L. Huber. June 1999, 84.
- High-Throughput Ribozyme Production. L. Bellon. February 1998, 26.
- RNA as a Small-Molecule Drug Target. D.J. Ecker. February 1998, 26-27.
- Emergence of Chemistry-Based Drug Discovery Companies. E. Field. February 1998, 27-28.
- Drug Discovery — Affinity and Beyond. N. Janjic. February 1998, 28.
- A Historical Perspective. M.J. Suto. February 1998, 28-39.
- Reliability Issues in High-Throughput Screening Systems. D.W. Brandt. February 1998, 30-32.
- Mainstreaming the Technology. M. Hediger. February 1998, 32,43.
- Innovations in Drug Discovery and Development: Sequencing by Hybridization. B. D'Elia and P. Hensler. July 1998, 30-31.
- From Discovery to Development, Part 1: Erasing the Line Between R&D. C. Scott and D. Wendt. November 1998, 22-26,53.
- Replacing Slab Gel Electrophoresis Methods with Capillary Electrophoresis for Quality Control and Stability Testing. S.H. Bowen and M.A. Schenerman. November 1998, 42-46,50.
- Systems Qualification for High-Performance Liquid Chromatography Systems. L. Huber. November 1998, 65-66,41.
- Combining ELISA, RP-HPLC, and SDS-PAGE to Define the Potency of a Complex Biologic. J.R. Zabrecky et al.. October 1998, 30-34.
- Implementing and Managing Calibration Training. D.M. Evans and J. Erickson. October 1998, 57-58.
- System Suitability Testing. S.S. Kuwahara. September 1998, 65-66.
- Establishing Calibration Intervals, Traceability, and Documentation. D.M. Evans and J. Erickson. June 1998, 73-74.
- Learning from Bioburden Count Distributions. D.W. Cooper. March 1998, 32-37.
- Pharmaceutical Excipients for the Stabilization of Proteins. D. Wong and J. Parasrampuria. November 1997, 52-61.
- Testing the Genetic Stability of Recombinant DNA Cell Banks. J.D. Kittle and B.J. Pimentel. October 1997, 48-51.
- A Virtual Roundtable. S.A. Montgomery D. Wendt, and C. Scott. September 1997, 32-42.
- In-House Development and Validation of Analytical Methods Standards for Biologics: Technical and Regulatory Concerns. W.J. White, Jr. S. Sutton-Jones, and C. Medina. August 1997, 20-24.
- Testing the Genetic Stability of Recombinant DNA Cell Banks. J.D. Kittle and B.J. Pimentel. August 1997, 30-35.
- Calibration and Validation of UV-Vis Absorption Spectrophotometers. A.C. Richardson and J.D. Messman. August 1997, 7.
- Characterization of Plasmid DNA Vectors for Use in Human Gene Therapy, Part 2. M. Marquet N.A. Horn, and J.A. Meek. June 1997, 40-45.
- Complete Automation of the Bacterial Endotoxin Assay. K.L. Williams. June 1997, 46-57.
- Characterization of Plasmid DNA Vectors for Use in Human Gene Therapy, Part 1. M. Marquet N.A. Horn, and J.A. Meek. May 1997, 42-50.
- Comparability (Bioequivalence) Testing of Monoclonal Antibodies. M.A. Schenerman and K. Phillips. April 1997, 20-26,72.

Outlier Testing: Its History and Application. S.S. Kuwahara. April 1997, 64–67.

Introducing a Manufacturing Execution System to a Biotechnology Environment. G. Roth. March 1997, 46–48.

An Immuno-Ligand Assay for the Detection and Quantitation of Contaminating Proteins in Recombinant Human Erythropoietin (r-HuEPO). I.A. Ghobrial D.T. Wong, and B.G. Sharma. January 1997, 42–45.

Glycobiology is Growing. J.C. Klock. July 1998, 31–33.

Homologous Recombination in CHO Cells. M. Reff. July 1998, 33–34.

High-Throughput Synthesis and DNA Chips. R.J. Molinari. July 1998, 34–36.

Chaos, Speed, and Value Curves: Capitalizing on Emerging Trends. M. Caple. July 1998, 36–38.

Animals in Research

Transgenic Protein Production: Part 3, Nuclear Transfer Technology. P. Rohricht and D. Ayares. November 1999, 56–60.

Transgenic Protein Production: Part 2, Process Economics. P. Rohricht. September 1999, 52–54.

Antisense Technology

Two Statistical Methods for Estimating Relative Potency of Bioassays. R. Reeve. July 2000, 54–60.

Reviewing Antisense Oligonucleotide Therapy: Part 2, Delivery Issues. S.K. Das and K.J. Miller. November 1999, 44–51.

Reviewing Antisense Oligonucleotide Therapy, Part 1: Action and Design. S.K. Das and K.J. Miller. October 1999, 42–48.

Nucleic Acid Drug Delivery, Part 1: Delivery Issues Related to Dividing Cells. S. Wu-Pong and D.A. Gewirtz. November 1998, 28–35.

Aseptic Processing

Isolators Revisited: The Current State of Implementation. J.E. Akers, Jr.. April 2000, 30–33.

Master Planning and Validation: Part 2: System Definition. J. Agalloco. April 2000, 34–38.

Detecting PEG-rHu MGDF in Rhesus Monkey Serum: An Enzyme-Linked Immunosorbent Assay. D. Chen et al.. April 2000, 48–50.

Tutorial: Exploiting the Poisson Distribution for Bioburden Investigations. D.W. Cooper. April 2000, 65–66.

Purifying the Sendai Virus in One Step Using Ion-Exchange Chromatography. J. Eveleth et al.. January 2000, 40–43.

Validation of a Cation-Exchange Method to Test for Residual Amounts of a Cleaning and Sanitizing Solution on Pharmaceutical Process Equipment. M.J. Shifflet and M. Shapiro. January 2000, 51–54.

Announcing USP Chapter <1046>, 'Cell and Gene Therapy Products'. S. Seaver. January 2000, 26–29.

CGMP Pharmaceutical Scale-Up: Part 2: Contractors and the Request for Proposal.

C. Pepper M. Patel, and H. Hartounian. October 1999, 36–40,55.

CGMP Pharmaceutical Scale-Up: Part 1: Design. C. Pepper M. Patel, and H. Hartounian. September 1999, 26–34.

The Use of Model Solvents for Evaluating Extractables from Filters Used to Process Pharmaceutical Products, Part 2: Assigning a Model Solvent. C.J. Weitzmann. May 1997, 72–78.

The Use of Model Solvents for Evaluating Extractables from Filters Used to Process Pharmaceutical Products, Part 1: Practical Considerations. C.J. Weitzmann. April 1997, 44–59.

Automation

Successful Technology Transfer: Lessons from Experience. C.J. Dale. October 2000, 48–56.

CGMP Pharmaceutical Scale-Up: Part 3: Automation. M. Patel C. Pepper, and H. Hartounian. November 1999, 52–54.

CGMP Pharmaceutical Scale-Up: Part 1: Design. C. Pepper M. Patel, and H. Hartounian. September 1999, 26–34.

From Discovery to Development: Part 2, Moving Forward. C. Scott and D. Wendt. January 1999, 26–30.

Validating Computerized Systems Developed Out of House: Reducing the Time It Takes. J. Gottfried. October 1998, 40–43.

Vendor View: Advances in Automation Software. Mac Williams. October 1999, 14–15.

Automation Technology Delivers Breakthrough Productivity. J. Salazar. September 1997, 56–57.

Complete Automation of the Bacterial Endotoxin Assay. K.L. Williams. June 1997, 46–57.

Biocompatibility Testing

See *Analytical Techniques*.

Biopreservation

The Basics of Laboratory-Scale Mammalian Cell Cryopreservation. L. Wolfenbarger. October 1998, 35–39.

Large-Scale Cryopreservation of Cells, Cell Components, and Biological Solutions. R. Wisniewski. September 1998, 42–49,61.

Developing Large-Scale Cryopreservation Systems for Biopharmaceutical Products. Richard Wisniewski. June 1998, 50–60.

Pharmaceutical Excipients for the Stabilization of Proteins. D. Wong and J. Parasrampur. November 1997, 52–61.

Bioreactor Design

Assessing a Disposable Bioreactor for Attachment-Dependent Cell Cultures. P.K.

Namdev and P. Lio. February 2000, 44–50.

Large-Scale Production of a Monoclonal IgM in a Hybridoma Suspension Culture. M.A.

Cacciuttolo et al.. April 1998, 20–27.

Using an External Vortex Flow Filtration

Device for Perfusion Cell Culture. J.I. Horwitz et al.. October 1997, 30–35.

Biosensors

Bioseparation

See *Separation and Purification*.

Biotechnology Basics

Biopharmaceutical Shipping: Moving at the Speed of Life. J. Johnson. March 2001, 34–36.

Demonstrating Product Comparability. H.K.B. Simmerman. September 2000, 58–62.

Viewpoint: A Marketing Solution for Emerging Biotechnology Companies. L.G. Lange. July 2000, 20–21.

The Evolving Role of Product Characterization During Development. J. Faulkner. June 2000, 26–34.

Detecting and Removing Porcine Viruses: To Prevent Contamination of Biopharmaceutical Raw Materials. B.J. Potts and W.J. Kivens. May 2000, 26–31.

Performance Qualification of Clean-in-Place Systems: Lessons from Experience in Multiproduct Biopharmaceutical Manufacturing. L. Hill. April 2000, 24–29.

Master Planning and Validation: Part 2: System Definition. J. Agalloco. April 2000, 34–38.

Viral Clearance Strategies for Biopharmaceutical Safety: Part 2: Filtration for Viral Clearance. H. Aranha. February 2001, 32–43.

Viral Clearance Strategies for Biopharmaceutical Safety: Part 1, General Considerations. H. Aranha. January 2001, 28–35.

Customized Ligands Optimize Affinity Chromatography Procedures. L-J Larsson. January 2001, 42–44.

From R&D to Licensing: What to Do and When to Do It. January 2001, 18–27.

Practices and Considerations in the Development of an Allogeneic Cellular Transplant. H.M. Nugent A.M. Woodland, and D. Deane. January 2001, 36–41.

Planning Ahead for Manufacturing Facility Changes: A Case Study in Outsourcing. M. Katz. January 2001, 46–47.

Making Better Decisions: Troubleshooting Biopharmaceutical Processes Using Problem Analysis. J.A. Myers. October 2000, 32–35.

Asilomar 2000: Symposium on Science, Ethics, and Society. C. Scott. March 2000, 10–14.

A Technology Transfer Story - Kangtai's Recombinant Hepatitis B Vaccine. E. Wang and J. Wu. July 1999, 20–21.

Biotechnology in Developing Countries: A Technology Imperative. H. Padh. July 1999, 18–19.

Announcing USP Chapter <1046>, 'Cell and Gene Therapy Products'. S. Seaver. January 2000, 26–29.

Viral Clearance Strategies for Biopharmaceutical Safety: Part 3: A Multifaceted Approach to Process Validation. S. Forbes and H. Aranha. May 2001, 42–54,90.

Women's Work: Women and Biotech in the

- 21st Century. L.D. McLeod. June 2001, 32-41.
- In Search of Standardized Definitions for Validation, Qualification, Verification, and Calibration. L. Huber. April 1999, 56-58.
- Transgenic Protein Production: The Technology and Major Players. P. Rohricht. March 1999, 46-48.
- From Discovery to Development, Part 1: Erasing the Line Between R&D. C. Scott and D. Wendt. November 1998, 22-26,53.
- The Basics of Laboratory-Scale Mammalian Cell Cryopreservation. L. Wolfenbarger. October 1998, 35-39.
- Environmental Control and Monitoring in Bulk Manufacturing Facilities for Biological Products. . May 1998, 84-89.
- Establishing a Calibration Management Program. D.M. Evans and J. Erickson. May 1998, 105-106.
- Analytical Standards and Controls. S.S. Kuwahara. April 1998, 57-58.
- Qualification of Legacy Equipment in Quality Control Laboratories. L.E. Little. March 1998, 61-62.
- Facility Qualification Studies. C. DeSain and C. Sutton. January 1998, 38-41.
- Qualification of Quality Control Laboratory Equipment. T.J. Pritchett. January 1998, 57-58.
- U.S. University Technology Transfer Offices: Finding Them on the World Wide Web. S.W. Compton. July 1997, 26-27.
- Industry Guides and Directories. C. Scott. July 1997, 18-20.
- Big Biotech: Designing the Plant of the Future. R.L. Williams. November 1997, 44-51.
- Pharmaceutical Excipients for the Stabilization of Proteins. D. Wong and J. Parasrampuria. November 1997, 52-61.
- Taking the Industry Into the Future: One Day At a Time. C. Scott. September 1997, 44-49.
- Quality Control for Ex Vivo Cell Therapy. G. Kielpinski et al.. January 1997, 34-40.
- Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products: Highlights from the New PDA Technical Report No. 34. R.E. Madsen. July 2001, 30-32.
- Business Issues**
- Viewpoint: The New Science of Investing. B.H. Rudolph and V. Aslam. September 2000, 20-22.
- Implementing the Biological Weapons Convention Protocol in the United States: What It Means to the Biopharmaceutical Industry. L.C. Klotz et al.. August 2000, 46-48.
- Viewpoint: A Marketing Solution for Emerging Biotechnology Companies. L.G. Lange. July 2000, 20-21.
- Preventing Discord in Outsourced Clinical Trials. H Marais. July 2000, 36-38.
- Risk Management and Liability for Biologics. C.S. Ryan and M.-L. Wan. July 2000, 40-42.
- Making Client Relationships Productive: Tips for the Contract Service Organization. R.S. Woodward. July 2000, 44-46.
- Keys to Developing an Effective Outsourcing Strategy:: Knowing When and Why You Outsource. R.S. Woodward. February 2000, 22-26.
- Restrictive Covenants: Protecting Confidential and Proprietary Information. C.A. Amalfe and K.R. Heslin. February 2000, 52-55.
- Software Helps Project Managers Organize Time, Human Resources, and Communications. D. Porubek. February 2000, 36-42.
- The Quality Agreement: Compliance Considerations in Selecting a Contract Manufacturer. G. Bobrowics. February 2001, 14-20.
- Outsourcing Industry Leaders Look Ahead to a Bright Future. L. Perry. February 2001, 30,48.
- "Science in the Mannerist Style" in Your Vested Interests. B.H. Rudolph and V. Aslam. February 2001, 68-70.
- Biotech Financial Markets are Hot but...: A Maturing Pipeline is the Key Driver of Contract Services for Biotech Companies. J. Miller and L. Perry. February 2001, 22-24.
- "Looking Back, Looking Ahead" in Outsourcing Outlook. J. Miller. February 2001, 60-62.
- Protecting Your Company's Trade Secrets. K.M. Parker and E.S. Pennington. October 1999, 50-52.
- Transgenic Protein Production: Part 2, Process Economics. P. Rohricht. September 1999, 52-54.
- Avoiding the Trademark Pitfalls of a Start-Up Company. R. Richards. August 1999, 26-30.
- Surveying the Field:Your Career in the Biopharmaceutical Industry. A. Muir. May 1999, 28-36.
- Preparing Your Project Team for Successful Outsourcing: Project Managers Face Communication Challenges. R.S. Woodward. May 1999, 58-60.
- Maturing Biomanufacturing Industry Offers Sponsors Clear Choices and Benefits. H.L. Levine and J.C. Miller. May 1999, 62-64.
- The Future and the Biotechnology Industry: New Trends in Pharmaceutical Development. M.D. Dibner. June 2001, 26-30.
- The Biotech Century Begins with a Boom — Then a Bust: Good, Bad, Good, Bad . . . What's Next?. G.S. Burrill. June 2001, 42-51.
- In Their Own Words: Five Executives on Success in the Industry. C.J. Prier Steffy. June 2001, 52-58.
- Our Ways Are Numbered: Surveying BioPharm's Readers. P.L. Cass. June 2001, 59-63.
- Spreadsheets: Let Them Collect Their Own Data! G. Forrest. March 1999, 40-44.
- The IRS and the Independent Contractor: Knowing the Rules of the Game. A.E. Schultz. July 2001, 24-26,70.
- Y2K Bug: A Millennium Debacle. K. Powell-Evans and B. Gibson. July 1998, 14-17,50.
- Corporate Capabilities: Company Profiles and Advertisements. . December 1999, 1-82.
- Preparing for Team Biologics Inspections: Improving Your Chances of Success. R.F. Tetzlaff. August 1998, 18-28.
- BIOTECHNOLITICS: An Entrepreneur's Political Agenda. C.B. Feldbaum. June 1998, 8-11.
- Becoming a Good and Valued Client: Dos and Don'ts for a Successful Outsourcing Relationship. R.S. Woodward. June 1998, 44-49.
- A Letter to the Industry. M. Glick. July 1997, 10-12.
- Contract Manufacturing: An Industry Reborn. D. Wendt and C. Scott. July 1997, 32-42.
- Demographics of Women in the San Diego Biopharmaceutical Industry. H.A. de Haan. February 1997, 8-10.
- Biotech: At Home on the World Wide Web?. D. Wendt. February 1997, 12-18.
- A Biotech Web Sampler. D. Wendt. February 1997, 20-22.
- Partnering for the Future: U.S. Biotechnology Companies Find Business Allies in Europe. R.S. Esposito. October 1997, 24-28.
- Biotechnology and Pharmaceuticals: 10 Years Later. M.D. Dibner. September 1997, 24-30.
- A Virtual Roundtable. S.A. Montgomery D. Wendt, and C. Scott. September 1997, 32-42.
- Automation Technology Delivers Breakthrough Productivity. J. Salazar. September 1997, 56-57.
- U.S. Government Technology Transfer Resources on the World Wide Web. S.W. Compton. September 1997, 58-59.
- Ready, Fire, Aim!: and Other Approaches to Product Approval. C.W. Cherry. September 1997, 62, 71.
- Before You Sign the Contract: Evaluating the Level of CRO Client Service. R.S. Woodward. June 1997, 26-32.
- Holland: A Gateway for Biopharmaceutical Companies. W. Schless. June 1997, 14-18.
- Patent News: The Doctrine of Equivalents. R. Schaffer and C.S. Ryan. June 1997, 10-12.
- Regional Technical Assistance and Business Development Programs. S. Compton. July 1998, 10-12,45.
- Science or Project Management: What (and Who) is More Important in Biotech?. T. Fitz. July 2001, 28-29.
- The Contract Services Landscape: Results from BioPharm's Second Outsourcing Survey. P.L. Cass. July 2001, 40-44.

Viewpoints

Business Matters Columns

- A Technology Transfer Story - Kangtai's Recombinant Hepatitis B Vaccine. E. Wang and J. Wu. July 1999, 20-21.
- Biotechnology in Developing Countries: A Technology Imperative. H. Padh. July 1999,

18–19.

Biotech at the End of the Century. G.S. Burrill. September 1999, 56–58.

Biotech's First Quarter '99 Showed Mixed Results. G.S. Burrill. June 1999, 34–38, 66. 1999 Predictions Are Optimistic. G.S. Burrill. March 1999, 20–23.

A Changing Environment. G.S. Burrill. July 1997, 28–30, 50.

Biotech's Biggest Year Ever. G.S. Burrill. May 1997, 30–36.

CANDAs

Cell Disruption

See *Downstream Processing*.

Cell Growth and Viability

Tutorial: Examining the Relationship Between Media and Light. W.H. Siegel. January 2000, 65–66.

Purifying the Sendai Virus in One Step Using Ion-Exchange Chromatography. J. Eveleth et al.. January 2000, 40–43.

Detection of Microbial Contamination in Cell Cultures Using a Laser Scanning System. A.O. Onadipe. April 2001, 38–40.

Industry trends in Biopharmaceutical production products and services showcase. G. Hess et al.30. July 1999, 22–30.

Replacing the Animal Component in Serum: Evaluating Raw Materials for Inclusion in Optimized Hybridoma Media. S.C. Peppers et al.. May 2001, 22–30.

Using an External Vortex Flow Filtration Device for Perfusion Cell Culture. J.I. Horwitz et al.. October 1997, 30–35.

Production-Scale Qualification of a Novel Cell Culture Medium Format. R. Radominski et al.. July 2001, 34–39.

Cell Harvesting

Using an External Vortex Flow Filtration Device for Perfusion Cell Culture. J.I. Horwitz et al.. October 1997, 30–35.

Cell Line Characterization

Strategies for Host Cell Protein Analysis. K. Hoffman. May 2000, 38–45.

Practices and Considerations in the Development of an Allogeneic Cellular Transplant. H.M. Nugent A.M. Woodland, and D. Deane. January 2001, 36–41.

Some Methods for Contamination Testing of a Master Cell Bank. M.d.R. Alemán et al.. June 2000, 48–52.

Cell Bank Validation: Comparing Points to Consider and ICH Guidelines. M.S. Lao. January 1999, 48–51.

Testing the Genetic Stability of Recombinant DNA Cell Banks. J.D. Kittle and B.J. Pimentel. October 1997, 48–51.

Testing the Genetic Stability of Recombinant DNA Cell Banks. J.D. Kittle and B.J. Pimentel. August 1997, 30–35.

In-Process Control for Large-Scale Animal Cell Culture. G. MacMichael. March 1997,

38–40.

Centrifugation

See *Downstream Processing*.

Chromatography

Validating the Sanitization of Chromatographic Resins: A Sample Case Study. M. H-S. and C. Broughton. April 2001, 26–30.

Industry Trends in Software for Biopharmaceutical Companies. C. Scott. February 1999, 22–32.

Minimizing Risks from Chromatography Media: Management of Raw Materials in Biopharmaceutical Production. R.M. Kennedy and L. Gonzales. May 2001, 56–58.

Ion-Exchange Displacement Chromatography: Scale-Up and Displacer Clearance for rHuBDNF. K.A. Barnhouse et al.. September 1999, 35–44.

Tutorial: Validation of HPLC Methods. L. Huber. March 1999, 64–66.

Systems Qualification for High-Performance Liquid Chromatography Systems. L. Huber. November 1998, 65–66, 41.

Multiuse Chromatography System: A Clean-in-Place Validation Case Study. P.A. Garipey R.S. Moore, and G. Sofer. September 1998, 32–36.

Regulatory Aspects of Column Chromatography in Biopharmaceutical Manufacturing: U.S. and EU Regulatory Attitudes Toward Change. M. Behizad and D. Baines. May 1998, 72–82.

Comparative Performances of 70 Ion-Exchange Chromatography Sorbents for Purification of Biomolecules. J. Dennis P. Levison, and C. Mumford. April 1998, 44–50.

Demonstrating Process Robustness for Chromatographic Purification of a Recombinant Protein. B.D. Kelley et al.. October 1997, 36–47.

Preparative Purification of Supercoiled Plasmid DNA for Therapeutic Applications. A.P. Green et al.. May 1997, 52–62.

Displacement Chromatography of Proteins Using Sucrose Octasulfate. S.M. Cramer et al.. May 1997, 64–70, 95.

Clean-in-Place Systems

See *Utility Design*.

Clean Rooms

See *Controlled Environment*

Clinical Trials

Biopharmaceutical Shipping: Moving at the Speed of Life. J. Johnson. March 2001, 34–36.

Preventing Discord in Outsourced Clinical Trials. H. Marais. July 2000, 36–38.

Becoming a Good and Valued Client: Dos and Don'ts for a Successful Outsourcing Relationship. R.S. Woodward. June 1998, 44–49.

Clinical Programs in Cutting-Edge Technologies: A Guide for Beginning the Development of Novel Therapies. M. Wade. May 1998, 52–56.

Computer Assistance Contributes to Successful Biotech Clinical Trials. R.D. Mamelok and J. Mandema. October 1997, 52–55.

Ready, Fire, Aim!: and Other Approaches to Product Approval. C.W. Chery. September 1997, 62, 71.

Before You Sign the Contract: Evaluating the Level of CRO Client Service. R.S. Woodward. June 1997, 26–32.

Computers: Hardware/Software

A Case Study in Compliance: Supporting 21 CFR Part 11 with a UV-Vis System. S. Bayerbach. November 2000, 48–50.

Preparing for Electronic Records and Electronic Signatures. M.L. Wyrick. November 2000, 10–12.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 2: Security Aspects for Systems and Applications. W. Winter and L. Huber. November 2000, 18–23.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 3: Ensuring Data Integrity in Electronic Records. W. Winter and L. Huber. November 2000, 24–27.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 4: Data Migration and Long-Term Archiving for Ready Retrieval. W. Winter and L. Huber. November 2000, 28–33.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 5: The Importance of Instrument Control and Data Acquisition. W. Winter and L. Huber. November 2000, 34–38.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 6: Biometric Identification — Limits and Possibilities. W. Winter and L. Humber. November 2000, 40–43.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 7: Making Legacy Systems Compliant. C. Nickel W. Winter, and L. Huber. November 2000, 44–47.

Implementing 21 CFR Part 11 in Analytical Laboratories: Glossary. L. Huber W. Winter, and P.L. Cass. November 2000, 56–61.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 3: Ensuring Data Integrity in Electronic Records. W. Winter and L. Huber. March 2000, 45–49.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 1: Overview and Requirements. W. Winter and L. Huber. November 2000, 14–17.

The Rule: Part 11 — Electronic Records; Electronic Signatures. . November 2000, 62–64.

Part 5: The Importance of Instrument Control and Data Acquisition. W. Winter and L. Huber. September 2000, 52–56.

Implementing 21 CFR Part 11 in Analytical Laboratories, Part 4: Data Migration and Long-Term Archiving for Ready Retrieval. L.

- Huber and W. Winter. June 2000, 58–64.
- Viewpoint: Electronic Submissions — Faster Assembly and Review. . January 2001, 12–16.
- Implementing 21 CFR Part 11 in Analytical Laboratories: Part 2, Security Aspects for Systems and Applications. W. Winter and L. Huber. January 2000, 44–50.
- Industry Trends in Software for Biopharmaceutical Companies. C. Scott. February 1999, 22–32.
- Qualifying High-Performance Capillary Electrophoresis Systems. G.A. Ross. November 1999, 81–82.
- CGMP Pharmaceutical Scale-Up: Part 3: Automation. M Patel C. Pepper, and H. Hartounian. November 1999, 52–54.
- Preparation and Qualification of Certified Reference Materials and Working Standards. L. Huber. June 1999, 84.
- Spreadsheets: Let Them Collect Their Own Data!. G. Forrest. March 1999, 40–44.
- Validating Computer Systems for Clinical Trials: Part 2, The Supplier Audit. G. Benghiat A. Miller, and P. Bleicher. March 1999, 51–54.
- Validating Computer Systems for Clinical Trials: Part 1, Leveraging Your Supplier's Verification Efforts. G. Benghiat A. Miller, and P. Bleicher. January 1999, 39–41.
- Validating Computerized Systems Developed Out of House: : Reducing the Time It Takes. J. Gottfried. October 1998, 40–43.
- Vendor View: Advances in Automation Software. Mac Williams. October 1999, 14–15.
- Computer Assistance Contributes to Successful Biotech Clinical Trials. R.D. Mamelok and J. Mandema. October 1997, 52–55.
- Automation Technology Delivers Break-through Productivity. J. Salazar. September 1997, 56–57.
- Introducing a Manufacturing Execution System to a Biotechnology Environment. G. Roth. March 1997, 46–48.
- Contamination Control**
- Ensuring Successful Validation: The Logical Steps to Efficient Cleaning Procedures. G. Amer and P. Deshmane. March 2001, 26–32.
- Detecting and Removing Porcine Viruses: To Prevent Contamination of Biopharmaceutical Raw Materials. B.J. Potts and W.J. Kivens. May 2000, 26–31.
- Production of Recombinant Collagen for Biomedical Devices. F. Ruggiero H. Chanut, and A. Fichard. May 2000, 32–37.
- Strategies for Host Cell Protein Analysis. K. Hoffman. May 2000, 38–45.
- Performance Qualification of Clean-in-Place Systems: Lessons from Experience in Multiproduct Biopharmaceutical Manufacturing. L. Hill. April 2000, 24–29.
- Isolators Revisited: The Current State of Implementation. J.E. Akers, Jr.. April 2000, 30–33.
- Master Planning and Validation: Part 2: System Definition. J. Agalloco. April 2000, 34–38.
- Tutorial: Exploiting the Poisson Distribution for Bioburden Investigations. D.W. Cooper. April 2000, 65–66.
- Purifying the Sendai Virus in One Step Using Ion-Exchange Chromatography. J. Eveleth et al.. January 2000, 40–43.
- Validation of a Cation-Exchange Method to Test for Residual Amounts of a Cleaning and Sanitizing Solution on Pharmaceutical Process Equipment. M.J. Shifflet and M. Shapiro. January 2000, 51–54.
- Validating the Sanitization of Chromatographic Resins: A Sample Case Study. M. H-S. and C. Broughton. April 2001, 26–30.
- Resistance of Porcine Circovirus to Gamma Irradiation. Z.M. Plavsic and S. Bolin. April 2001, 32–36.
- Detection of Microbial Contamination in Cell Cultures Using a Laser Scanning System. A.O. Onadipe. April 2001, 38–40.
- Some Methods for Contamination Testing of a Master Cell Bank. M.d.R. Alemán et al.. June 2000, 48–52.
- Inactivation of Viruses and Mycoplasmas in Fetal Bovine Serum Using 56 °C Heat. J. Smith M. Plavsic, and D.J. Danner. June 1999, 50–52.
- Bioburden Determinations: Most Probable Number or Colony Counting?. D.W. Cooper. June 1999, 53–55, 90.
- Blow-Fill-Seal Technology: Design Optimization of a Particulate Control System. J. Price. April 1999, 25–29, 43.
- Environmental Control and Monitoring in Bulk Manufacturing Facilities for Biological Products. . May 1998, 84–89.
- A Bovine Spongiform Encephalopathy Validation Study for Aprotinin and Bovine Serum Albumin. M. Blum et al.. April 1998, 28–34.
- Assessment of Risk of Bovine Spongiform Encephalopathy in Pharmaceutical Products, Part 2: Example Risk Assessment for a Hypothetical Product. Pharmaceutical Research and Manufacturers of America BSE Committee. March 1998, 18–30.
- Learning from Bioburden Count Distributions. D.W. Cooper. March 1998, 32–37.
- Assessment of Risk of Bovine Spongiform Encephalopathy in Pharmaceutical Products, Part 1. Pharmaceutical Research and Manufacturers of America BSE Committee. January 1998, 20–31.
- An Immuno-Ligand Assay for the Detection and Quantitation of Contaminating Proteins in Recombinant Human Erythropoietin (r-HuEPO). I.A. Ghobrial D.T. Wong, and B.G. Sharma. January 1997, 42–45.
- Contract Services**
- BioPharm Outsourcing Survey: Version 1.0. S.A. Montgomery. September 1998, 28–30.
- Client Confidentiality and Intellectual Property: Key Challenges in Outsourcing. M. Renn K. Hall, and C. Younger. November 2000, 52–54.
- Pharmaceutical Companies Provide Unique Contract Service Capabilities. S. Fox. July 2000, 30–34.
- Preventing Discord in Outsourced Clinical Trials. H Marais. July 2000, 36–38.
- Risk Management and Liability for Biologics. C.S. Ryan and M.-L. Wan. July 2000, 40–42.
- Making Client Relationships Productive: Tips for the Contract Service Organization. R.S. Woodward. July 2000, 44–46.
- Keys to Developing an Effective Outsourcing Strategy.: Knowing When and Why You Outsource. R.S. Woodward. February 2000, 22–26.
- The Quality Agreement: Compliance Considerations in Selecting a Contract Manufacturer. G. Bobrowics. February 2001, 14–20.
- Outsourcing Industry Leaders Look Ahead to a Bright Future. L. Perry. February 2001, 30, 48.
- Project Management of Small R&D Companies, Part 2: Perspectives from a Large CRO. F Beddia et al.. March 2001, 38–40.
- Project Management of Small R&D Companies, Part 1: Perspective from a Large CRO. F. Beddia et al.. February 2001, 26–28.
- Biotech Financial Markets are Hot but...: A Maturing Pipeline is the Key Driver of Contract Services for Biotech Companies. J. Miller and L. Perry. February 2001, 22–24.
- "Looking Back, Looking Ahead" in Outsourcing Outlook. J. Miller. February 2001, 60–62.
- Customized Ligands Optimize Affinity Chromatography Procedures. L-J Larsson. January 2001, 42–44.
- Planning Ahead for Manufacturing Facility Changes: A Case Study in Outsourcing. M. Katz. January 2001, 46–47.
- "Technical Innovations in Data Management" in Outsourcing Outlook. J. Miller and L. Michalski. November 2000, 16–20.
- Successful Technology Transfer: Lessons from Experience. C.J. Dale. October 2000, 48–56.
- How to Identify Vendor Risk. J. Miller and L. Michalski. October 2000, 20–25.
- The Reemergence of the Biopharmaceutical Contract Manufacturing Industry. R.L. McKown. May 1999, 54–57.
- Preparing Your Project Team for Successful Outsourcing: Project Managers Face Communication Challenges. R.S. Woodward. May 1999, 58–60.
- Maturing Biomanufacturing Industry Offers Sponsors Clear Choices and Benefits. H.L. Levine and J.C. Miller. May 1999, 62–64.
- Validating Computerized Systems Developed Out of House: : Reducing the Time It Takes. J. Gottfried. October 1998, 40–43.
- Outsourcing Biopharmaceutical Manufacturing Operations. S.H. Messing. June 1998, 28–30.
- Considerations for Selecting a Contract Biomanufacturer. D.M. Rehkop. June 1998, 32–34.
- Becoming a Good and Valued Client: Dos

and Don'ts for a Successful Outsourcing Relationship. R.S. Woodward. June 1998, 44–49.

Contract Manufacturing: An Industry Reborn. D. Wendt and C. Scott. July 1997, 32–42.

A Virtual Roundtable. S.A. Montgomery D. Wendt, and C. Scott. September 1997, 32–42.

Before You Sign the Contract: Evaluating the Level of CRO Client Service. R.S. Woodward. June 1997, 26–32.

The Contract Services Landscape: Results from BioPharm's Second Outsourcing Survey. P.L. Cass. July 2001, 40–44.

Controlled Environments

Isolators Revisited: The Current State of Implementation. J.E. Akers, Jr.. April 2000, 30–33.

Tutorial: Exploiting the Poisson Distribution for Bioburden Investigations. D.W. Cooper. April 2000, 65–66.

An Introduction to Biohazard Safety Cabinetry. R.F. Lohser and L. XiangQian. April 2001, 42–43.

Blow-Fill-Seal Technology: Design Optimization of a Particulate Control System. J. Price. April 1999, 25–29,43.

Validating a Refrigerator-Freezer. P.A. Cloud. November 1998, 47–50.

Environmental Control and Monitoring in Bulk Manufacturing Facilities for Biological Products. . May 1998, 84–89.

Depyrogenation

Endotoxin Reduction in Macromolecular Solutions: Two Case Studies. S.P. Crump et al.. March 1997, 32–37.

Diagnostics

DNA Assay Methods

See *Analytical Techniques*.

DNA Probes

See *Analytical Techniques*.

DNA Synthesis

Ion-Exchange Displacement Chromatography: Scale-Up and Displacer Clearance for rHuBDNF. K.A. Barnthouse et al.. September 1999, 35–44.

Cancer Gene Therapy Using Plasmid DNA: Pharmacokinetics and Safety Evaluation of an IL-2 Plasmid DNA Expression Vector in Rodents and Nonhuman Primates. S.E. Parker et al.. April 1999, 18–23.

Science or Project Management: What (and Who) is More Important in Biotech?. T. Fitz. July 2001, 28–29.

Documentation

Restrictive Covenants: Protecting Confidential and Proprietary Information. C.A. Amalfe and K.R. Heslin. February 2000, 52–55.

Downstream Processing

Inactivation of Several Bovine Viruses in Fetal Bovine Serum Using pH Adjustments. . November 2000, 34–38.

Differential Scanning Calorimetry: A Practical Tool for Elucidating Stability of Liquid Biopharmaceuticals. R.L. Remmele, Jr. and W.R. Gombotz. June 2000, 36–46.

Effect of Heat Treatment on Four Viruses Inoculated into BSA and Bovine Transferrin Solution. Z.M. Plavsic. June 2000, 54–56.

Detecting and Removing Porcine Viruses: To Prevent Contamination of Biopharmaceutical Raw Materials. B.J. Potts and W.J. Kivens. May 2000, 26–31.

Using Molecular Beacons to Quantify Low Levels of Type I Endonuclease Activity. R.J. Strouse et al.. April 2000, 40–47.

Protein Stability in Pulmonary Delivery Formulations: A Review. R. Krishnamurthy. March 1999, 34–38.

Multiuse Chromatography System: A Clean-in-Place Validation Case Study. P.A. Garipey R.S. Moore, and G. Sofer. September 1998, 32–36.

Large-Scale Cryopreservation of Cells, Cell Components, and Biological Solutions. R. Wisniewski. September 1998, 42–49,61.

Elements of Downstream Bioprocess Validation. N.M. Lugo. June 1998, 18–26.

Comparative Performances of 70 Ion-Exchange Chromatography Sorbents for Purification of Biomolecules. J. Dennis P. Levison, and C. Mumford. April 1998, 44–50.

Stability of Proteins during Manufacture and Release from Biodegradable Polymers. R. Krishnamurthy and J.A. Lumpkin. January 1998, 32–36.

Demonstrating Process Robustness for Chromatographic Purification of a Recombinant Protein. B.D. Kelley et al.. October 1997, 36–47.

Preparative Purification of Supercoiled Plasmid DNA for Therapeutic Applications. A.P. Green et al.. May 1997, 52–62.

Displacement Chromatography of Proteins Using Sucrose Octasulfate. S.M. Cramer et al.. May 1997, 64–70, 95.

Cryogranulation: A Potential New Final Process for Bulk Drug Substances. D.J. Schmidt and M.J. Akers. April 1997, 28–32.

The Role of Charge in the Retention of DNA by Charged Cellulose-Based Depth Filters. N. Dorsey J. Eschrich, and G. Cyr. January 1997, 46–49.

Drug Discovery

See *Analytical Techniques*.

Drug Formulation and Delivery

Differential Scanning Calorimetry: A Practical Tool for Elucidating Stability of Liquid Biopharmaceuticals. R.L. Remmele, Jr. and W.R. Gombotz. June 2000, 36–46.

Production of Recombinant Collagen for Biomedical Devices. F. Ruggiero H. Chanut, and A. Fichard. May 2000, 32–37.

Reviewing Antisense Oligonucleotide Therapy: Part 2, Delivery Issues. S.K. Das and K.J. Miller. November 1999, 44–51.

Nonviral Gene Delivery Systems: Part 2, Physical Characterization. T.J. Anchordoquy. September 1999, 46–51.

Nonviral Gene Delivery Systems, Part 1: Physical Stability. T.J. Anchordoquy. June 1999, 42–48.

Protein Stability in Pulmonary Delivery Formulations: A Review. R. Krishnamurthy. March 1999, 34–38.

Nucleic Acid Drug Delivery, Part 2.: Delivery to the Brain. S. Wu-Pong and D.A. Gewirtz. January 1999, 32–36.

Nucleic Acid Drug Delivery, Part 1: Delivery Issues Related to Dividing Cells. S. Wu-Pong and D.A. Gewirtz. November 1998, 28–35.

Developing Large-Scale Cryopreservation Systems for Biopharmaceutical Products. Richard Wisniewski. June 1998, 50–60.

Therapeutic Delivery Issues in Gene Therapy, Part 2: Targeting Approaches. D.A. Parasrampur and C.A. Hunt. May 1998, 58–70.

Environmental Control and Monitoring in Bulk Manufacturing Facilities for Biological Products. . May 1998, 84–89.

Therapeutic Delivery Issues in Gene Therapy, Part 1: Vectors. D.A. Parasrampur and C.A. Hunt. March 1998, 38–45.

Stability of Proteins during Manufacture and Release from Biodegradable Polymers. R. Krishnamurthy and J.A. Lumpkin. January 1998, 32–36.

Computer Assistance Contributes to Successful Biotech Clinical Trials. R.D. Mamelok and J. Mandema. October 1997, 52–55.

Drug Master Files

See *Master Files*.

Education and Training

Performance: The Goal of Training: or Why Training Is Not Always the Answer February 2001, 44–46.

Defining Your GMP Training Program with a Training Procedure. J.L. Vesper. November 2000, 28–32.

Biopharmaceutical Shipping: Moving at the Speed of Life. J. Johnson. March 2001, 34–36.

Improving the ESD Procedure for Outlier Testing. M.A. Djauhari. March 2001, 42–46.

Tutorial: The Importance of Time Variables in Temperature Studies. P.A. Hugunin and G. Straub. February 2000, 73–74.

Software Helps Project Managers Organize Time, Human Resources, and Communications. D. Porubek. February 2000, 36–42.

Viewpoint: Electronic Submissions — Faster Assembly and Review. . January 2001, 12–16.

Making Better Decisions.: Troubleshooting Biopharmaceutical Processes Using Problem Analysis. J.A. Myers. October 2000, 32–35.

A Guide to Determining Sample Sizes and Outlier Criteria in Analytical Investigations.

- J.D. Hofer and E.C. Rickard. May 2001, 32–41, 68.
- Improving Your Training Program. B.K. Immel. August 1999, 31–34.
- A Practical Approach to Investigating GMP Failures. J.F. Huzsoll. August 1999, 39–42.
- GMP, Compliance, and Regulatory Resources Shine on the Worldwide Web. C. Scott. August 1999, 46–48.
- Technical Note:: An Exact Test for Outlier Detection. M.A. Djauhari. June 1999, 56–59.
- Women's Work: Women and Biotech in the 21st Century. L.D. McLeod. June 2001, 32–41.
- A Practical Guide to Executing Validation Protocols. G.S. Hodgson. April 1999, 30–32.
- Validating a Refrigerator-Freezer. P.A. Cloud. November 1998, 47–50.
- Implementing and Managing Calibration Training. D.M. Evans and J. Erickson. October 1998, 57–58.
- System Suitability Testing. S.S. Kuwahara. September 1998, 65–66.
- Preparing for Team Biologics Inspections: Improving Your Chances of Success. R.F. Tetzlaff. August 1998, 18–28.
- GMP Compliance from a Production Manager's Point of View. M. Pemberton. August 1998, 34–37.
- The Nuts and Bolts of FDA Inspections: Before, During, and After. J.R. Christensen. August 1998, 44–46.
- Validating a Laboratory Incubator. P.A. Cloud. November 1997, 30, 39–42.
- Taking the Industry Into the Future: One Day At a Time. C. Scott. September 1997, 44–49.
- BioPharm Conference '97 Report: Conference Celebrates Magazine's 10th year. C. Scott and D. Wendt. September 1997, 78–81.
- The IRS and the Independent Contractor: Knowing the Rules of the Game. A.E. Schultz. July 2001, 24–26, 70.
- Electrophoresis**
- Replacing Slab Gel Electrophoresis Methods with Capillary Electrophoresis for Quality Control and Stability Testing. S.H. Bowen and M.A. Schenerman. November 1998, 42–46, 50.
- Combining ELISA, RP-HPLC, and SDS-PAGE to Define the Potency of a Complex Biologic. J.R. Zabrecky et al.. October 1998, 30–34.
- Emerging Technologies**
- Corn Seed Production of Therapeutic Proteins Moves Forward: One Company's Experience. J. Baez D. Russell, and J. Craig. August 2000, 50–54.
- Differential Scanning Calorimetry: A Practical Tool for Elucidating Stability of Liquid Biopharmaceuticals. R.L. Remmele, Jr. and W.R. Gombotz. June 2000, 36–46.
- Viral Clearance Strategies for Biopharmaceutical Safety: Part 2: Filtration for Viral Clearance. H. Aranha. February 2001, 32–43.
- Viral Clearance Strategies for Biopharmaceutical Safety: Part 1, General Considerations. H. Aranha. January 2001, 28–35.
- Encapsulated Antibody-Producing Cells for Long-Term Passive Immunotherapy. M. Pelegrin et al.. October 1999, 32–35.
- Second Generation Combinatorial Chemistry. A. Baxter. February 1998, 24–25.
- Trangenics Go Commercial. M. Young et al.. July 1998, 24–28.
- Innovations in Drug Discovery and Development: Sequencing by Hybridization. B. D'Elia and P. Hensler. July 1998, 30.
- Innovations in Drug Discovery and Development: Microbial Biodiversity Provides New Leads for Drug Discovery. T.J. Bruggeman. July 1999, 30–31.
- High-Throughput Synthesis and DNA Chips. R.J. Molinari. July 1998, 34–36.
- From Discovery to Development, Part 1: Erasing the Line Between R&D. C. Scott and D. Wendt. November 1998, 22–26, 53.
- Clinical Programs in Cutting-Edge Technologies: A Guide for Beginning the Development of Novel Therapies. M. Wade. May 1998, 52–56.
- BioRegion: Using a Virtual Enterprise to Foster a Regional Biotech Industry. U. Jensen. May 1998, 20–21.
- Therapeutic Delivery Issues in Gene Therapy, Part 2: Targeting Approaches. D.A. Parasrampurua and C.A. Hunt. May 1998, 58–70.
- Therapeutic Delivery Issues in Gene Therapy, Part 1: Vectors. D.A. Parasrampurua and C.A. Hunt. March 1998, 38–45.
- Patenting Issues in Functional Genomics. C.R. Sutton. January 1998, 42–44.
- Biotech: At Home on the World Wide Web?. D. Wendt. February 1997, 12–18.
- A Biotech Web Sampler. D. Wendt. February 1997, 20–22.
- A Virtual Roundtable. S.A. Montgomery D. Wendt, and C. Scott. September 1997, 32–42.
- Safety Considerations and Quality Assurance for Xenotransplantation. L.J. Schiff. August 1997, 48–50.
- Production of Biopharmaceutical Proteins in the Milk of Transgenic Dairy Animals. M.W. Young. June 1997, 34–38.
- Cryogranulation: A Potential New Final Process for Bulk Drug Substances. D.J. Schmidt and M.J. Akers. April 1997, 28–32.
- Glycobiology is Growing. J.C. Klock. July 1998, 31–33.
- Homologous Recombination in CHO Cells. M. Reff. July 1998, 33–34.
- Chaos, Speed, and Value Curves: Capitalizing on Emerging Trends. M. Caple. July 1998, 36–38.
- Environmental Issues**
- Blow-Fill-Seal Technology: Design Optimization of a Particulate Control System. J. Price. April 1999, 25–29, 43.
- The Elimination of Environmental Assessments for Biologically Derived Drug Products. T.J. Malott. September 1997, 50–54.
- Environmental Protection Agency**
- Enzymes**
- Enzyme Immobilization**
See Immobilized Cell Culture.
- Enzyme-Linked Immunosorbent Assay**
See Analytical Techniques.
- Establishment License**
See Regulatory Affairs.
- European Economic Community**
See International Business.
- Expression Systems**
- Transgenic Protein Production: The Technology and Major Players. P. Rohricht. March 1999, 46–48.
- Trangenics Go Commercial. M. Young et al.. July 1998, 24–28.
- Therapeutic Delivery Issues in Gene Therapy, Part 2: Targeting Approaches. D.A. Parasrampurua and C.A. Hunt. May 1998, 58–70.
- Therapeutic Delivery Issues in Gene Therapy, Part 1: Vectors. D.A. Parasrampurua and C.A. Hunt. March 1998, 38–45.
- Testing the Genetic Stability of Recombinant DNA Cell Banks. J.D. Kittle and B.J. Pimentel. October 1997, 48–51.
- Testing the Genetic Stability of Recombinant DNA Cell Banks. J.D. Kittle and B.J. Pimentel. August 1997, 30–35.
- Facility Design and Construction**
- CGMP Pharmaceutical Scale-Up: Part 4: Installation, Commissioning, Development. C. Pepper M. ,H. Patel ,Hartounian, and H. Hartounian. February 2000, 28–34.
- Master Planning and Validation: Part 1: Anatomy of a Validation Master Plan. J. Agalloco. March 2000, 40–44.
- Tutorial: The Importance of Time Variables in Temperature Studies. P.A. Hugunin and G. Straub. February 2000, 73–74.
- Successful Technology Transfer: Lessons from Experience. C.J. Dale. October 2000, 48–56.
- Biotech Facilities for the Future. L.J. Stillman. October 1999, 16–18.
- CGMP Pharmaceutical Scale-Up: Part 2: Contractors and the Request for Proposal. C. Pepper M. Patel, and H. Hartounian. October 1999, 36–40, 55.
- CGMP Pharmaceutical Scale-Up: Part 1: Design. C. Pepper M. Patel, and H. Hartounian. September 1999, 26–34.
- The Reemergence of the Biopharmaceutical Contract Manufacturing Industry. R.L. McKown. May 1999, 54–57.
- The Integration of Design, Construction, and Validation: Solving a Validation Challenge.

- J.N. Odum. November 1998, 36–41.
 Facility Qualification Studies. C. DeSain and C. Sutton. January 1998, 38–41.
 Production of Biopharmaceutical Proteins in the Milk of Transgenic Dairy Animals. M.W. Young. June 1997, 34–38.
 A Rapid Validation Approach: Reducing the Time and Costs Associated with Validation. S. Buchholz. January 1997, 50–53.

Federal Policies

See *Government Policies*.

Filtration

- Viral Clearance Strategies for Biopharmaceutical Safety: Part 2: Filtration for Viral Clearance. H. Aranha. February 2001, 32–43.
 Viral Clearance Strategies for Biopharmaceutical Safety: Part 1, General Considerations. H. Aranha. January 2001, 28–35.
 The Use of Model Solvents for Evaluating Extractables from Filters Used to Process Pharmaceutical Products, Part 2: Assigning a Model Solvent. C.J. Weitzmann. May 1997, 72–78.
 The Role of Charge in the Retention of DNA by Charged Cellulose-Based Depth Filters. N. Dorsey J. Eschrich, and G. Cyr. January 1997, 46–49.

Financial Strategies

- The Industrial Production Costs of Recombinant Therapeutic Proteins Expressed in Transgenic Corn. D. Mison and J. Curling. May 2000, 48–54.
 Restrictive Covenants: Protecting Confidential and Proprietary Information. C.A. Amalfe and K.R. Heslin. February 2000, 52–55.
 "Science in the Mannerist Style" in Your Vested Interests. B.H. Rudolph and V. Aslam. February 2001, 68–70.
 Biotech Financial Markets are Hot but...: A Maturing Pipeline is the Key Driver of Contract Services for Biotech Companies. J. Miller and L. Perry. February 2001, 22–24.
 The Future and the Biotechnology Industry: New Trends in Pharmaceutical Development. M.D. Dibner. June 2001, 26–30.
 Partnering for the Future: U.S. Biotechnology Companies Find Business Allies in Europe. R.S. Esposito. October 1997, 24–28.

Gene Therapy

- Encapsulated Antibody-Producing Cells for Long-Term Passive Immunotherapy. M. Pelegrin et al.. October 1999, 32–35.
 Nonviral Gene Delivery Systems: Part 2, Physical Characterization. T.J. Anchordoquy. September 1999, 46–51.
 Nonviral Gene Delivery Systems, Part 1: Physical Stability. T.J. Anchordoquy. June 1999, 42–48.
 Cancer Gene Therapy Using Plasmid DNA: Pharmacokinetics and Safety Evaluation of an IL-2 Plasmid DNA Expression Vector in Rodents and Nonhuman Primates. S.E. Parker et al.. April 1999, 18–23.

- Nucleic Acid Drug Delivery, Part 2:: Delivery to the Brain. S. Wu-Pong and D.A. Gewirtz. January 1999, 32–36.
 Nucleic Acid Drug Delivery, Part 1: Delivery Issues Related to Dividing Cells. S. Wu-Pong and D.A. Gewirtz. November 1998, 28–35.
 The Basics of Laboratory-Scale Mammalian Cell Cryopreservation. L. Wolfenbarger. October 1998, 35–39.
 Therapeutic Delivery Issues in Gene Therapy, Part 2: Targeting Approaches. D.A. Parasrampur and C.A. Hunt. May 1998, 58–70.
 Therapeutic Delivery Issues in Gene Therapy, Part 1: Vectors. D.A. Parasrampur and C.A. Hunt. March 1998, 38–45.
 A Virtual Roundtable. S.A. Montgomery D. Wendt, and C. Scott. September 1997, 32–42.
 The Future of Quality Control for Gene and Cell Therapies. S.S. Kuwahara. September 1997, 64–65.
 Characterization of Plasmid DNA Vectors for Use in Human Gene Therapy, Part 2. M. Marquet N.A. Horn, and J.A. Meek. June 1997, 40–45.
 Characterization of Plasmid DNA Vectors for Use in Human Gene Therapy, Part 1. M. Marquet N.A. Horn, and J.A. Meek. May 1997, 42–50.
 Preparative Purification of Supercoiled Plasmid DNA for Therapeutic Applications. A.P. Green et al.. May 1997, 52–62.

Glycosylation

See *Posttranslational Processing*.

Good Laboratory Practices

- Two Statistical Methods for Estimating Relative Potency of Bioassays. R. Reeve. July 2000, 54–60.
 Implementing 21 CFR Part 11 in Analytical Laboratories, Part 4: Data Migration and Long-Term Archiving for Ready Retrieval. L. Huber and W. Winter. June 2000, 58–64.
 Implementing 21 CFR Part 11 in Analytical Laboratories: Part 2, Security Aspects for Systems and Applications. W. Winter and L. Huber. January 2000, 44–50.
 Qualifying High-Performance Capillary Electrophoresis Systems. G.A. Ross. November 1999, 81–82.
 Qualifying High-Performance Liquid Chromatography/Mass Spectrometry Systems. W.P. Duncan. October 1999, 65–66.
 A Guide to Determining Sample Sizes and Outlier Criteria in Analytical Investigations. J.D. Hofer and E.C. Rickard. May 2001, 32–41, 68.
 Qualification of UV-Visible Spectrophotometers — Practical Implementation. T. Owen. January 1999, 62–66, 25.
 Ensuring Laboratory Compliance. R.H. Johnson. August 1998, 30–32.
 A Holistic Approach to GLP and cGMP Compliance. J.R. Christensen. January 1997, 16–18.

Good Manufacturing Practices

- Performance: The Goal of Training: or Why Training Is Not Always the Answer February 2001, 44–46.
 A Case Study in Compliance: Supporting 21 CFR Part 11 with a UV-Vis System. S. Bayerbach. November 2000, 48–50.
 Preparing for Electronic Records and Electronic Signatures. M.L. Wyrick. November 2000, 10–12.
 Implementing 21 CFR Part 11 in Analytical Laboratories: Part 2: Security Aspects for Systems and Applications. W. Winter and L. Huber. November 2000, 18–23.
 Implementing 21 CFR Part 11 in Analytical Laboratories: Part 3: Ensuring Data Integrity in Electronic Records. W. Winter and L. Huber. November 2000, 24–27.
 Implementing 21 CFR Part 11 in Analytical Laboratories: Part 4: Data Migration and Long-Term Archiving for Ready Retrieval. W. Winter and L. Huber. November 2000, 28–33.
 Implementing 21 CFR Part 11 in Analytical Laboratories: Part 5: The Importance of Instrument Control and Data Acquisition. W. Winter and L. Huber. November 2000, 34–38.
 Implementing 21 CFR Part 11 in Analytical Laboratories: Part 6: Biometric Identification — Limits and Possibilities. W. Winter and L. Huber. November 2000, 40–43.
 Implementing 21 CFR Part 11 in Analytical Laboratories: Part 7: Making Legacy Systems Compliant. C. Nickel W. Winter, and L. Huber. November 2000, 44–47.
 "Complying with Part 11 — Revisited" in GMP Issues. B.K. Immel. November 2000, 52–55.
 Ensuring Successful Validation: The Logical Steps to Efficient Cleaning Procedures. G. Amer and P. Deshmane. March 2001, 26–32.
 Implementing 21 CFR Part 11 in Analytical Laboratories: Part 1: Overview and Requirements. W. Winter and L. Huber. November 2000, 14–17.
 The Rule: Part 11 — Electronic Records; Electronic Signatures. . November 2000, 62–64.
 GMP, Compliance, and Regulatory Resources on the Worldwide Web:: An Update. C. Scott and P.L. Cass. October 2000, 58–62.
 Part 5: The Importance of Instrument Control and Data Acquisition. W. Winter and L. Huber. September 2000, 52–56.
 Two Statistical Methods for Estimating Relative Potency of Bioassays. R. Reeve. July 2000, 54–60.
 Implementing 21 CFR Part 11 in Analytical Laboratories, Part 4: Data Migration and Long-Term Archiving for Ready Retrieval. L. Huber and W. Winter. June 2000, 58–64.
 Process Hazard Analysis and Critical Control Point Identification. C. DeSain and C. Sutton. October 2000, 36–40.
 When Things Go Wrong, Part 1: The Consequences of Noncompliance. B.K. Immel.

- August 2000, 38–44.
- Revisiting Validation: Continuing Concerns, New Challenges. G. Sofer. October 1999, 26–30.
- Qualifying High-Performance Liquid Chromatography/Mass Spectrometry Systems. W.P. Duncan. October 1999, 65–66.
- Validating Critical Reagents Used in CGMP Analytical Testing: Ensuring Method Integrity and Reliable Assay Performance. N. Ritter and M. Wiebe. May 2001, 12–21.
- Minimizing Risks from Chromatography Media: Management of Raw Materials in Biopharmaceutical Production. R.M. Kennedy and L. Gonzales. May 2001, 56–58.
- Improving Your Training Program. B.K. Immel. August 1999, 31–34.
- The Compliance Costs of Hasty Process Development. G. Bobrowicz. August 1999, 35–38.
- A Practical Approach to Investigating GMP Failures. J.F. Huzsoll. August 1999, 39–42.
- GMP, Compliance, and Regulatory Resources Shine on the Worldwide Web. C. Scott. August 1999, 46–48.
- Harmonizing Validation Processes - Beyond Common Goals. R. Price. August 1999, 14–16.
- Preparation and Qualification of Certified Reference Materials and Working Standards. L. Huber. June 1999, 84.
- Cell Bank Validation: Comparing Points to Consider and ICH Guidelines. M.S. Lao. January 1999, 48–51.
- Qualification of UV-Visible Spectrophotometers — Practical Implementation. T. Owen. January 1999, 62–66, 25.
- Responding to FDA-483s and Warning Letters. D.L. Chesney and A.E. Kelley. October 1998, 26–29.
- Stepwise Implementation of CGMPs: A “GSP” Approach. L.E. Little. September 1998, 37–41.
- Preparing for Team Biologics Inspections: Improving Your Chances of Success. R.F. Tetzlaff. August 1998, 18–28.
- Ensuring Laboratory Compliance. R.H. Johnson. August 1998, 30–32.
- GMP Compliance from a Production Manager’s Point of View. M. Pemberton. August 1998, 34–37.
- Setting Biopharmaceutical Specifications. J. Cohen and M. Busch. August 1998, 38–42.
- Beating the Documentation Blues. B.K. Immel. August 1998, 47–51.
- Considerations for Selecting a Contract Biomanufacturer. D.M. Rehkop. June 1998, 32–34.
- Big Biotech: Designing the Plant of the Future. R.L. Williams. November 1997, 44–51.
- The Future of Quality Control for Gene and Cell Therapies. S.S. Kuwahara. September 1997, 64–65.
- Current Trends: Impact of the Well-Characterized Regulatory Paradigm. L. Little. August 1997, 8–9, 12, 58.
- In-House Development and Validation of Analytical Methods Standards for Biologics: Technical and Regulatory Concerns. W.J. White, Jr. S. Sutton-Jones, and C. Medina. August 1997, 20–24.
- The Use of Model Solvents for Evaluating Extractables from Filters Used to Process Pharmaceutical Products, Part 2: Assigning a Model Solvent. C.J. Weitzmann. May 1997, 72–78.
- The Use of Model Solvents for Evaluating Extractables from Filters Used to Process Pharmaceutical Products, Part 1: Practical Considerations. C.J. Weitzmann. April 1997, 44–59.
- In-Process Control for Large-Scale Animal Cell Culture. G. MacMichael. March 1997, 38–40.
- Introducing a Manufacturing Execution System to a Biotechnology Environment. G. Roth. March 1997, 46–48.
- Quality Control for Ex Vivo Cell Therapy. G. Kiepinski et al.. January 1997, 34–40.
- A Rapid Validation Approach: Reducing the Time and Costs Associated with Validation. S. Buchholz. January 1997, 50–53.
- A Holistic Approach to GLP and cGMP Compliance. J.R. Christensen. January 1997, 16–18.
- Government Policies**
- Implementing 21 CFR Part 11 in Analytical Laboratories: Part 3: Ensuring Data Integrity in Electronic Records. W. Winter and L. Huber. March 2000, 45–49.
- GMP, Compliance, and Regulatory Resources on the Worldwide Web:: An Update. C. Scott and P.L. Cass. October 2000, 58–62.
- Implementing the Biological Weapons Convention Protocol in the United States: What It Means to the Biopharmaceutical Industry. L.C. Klotz et al.. August 2000, 46–48.
- The FDA Regulatory Methods Validation Program for NDAs and ANDAs. T. Layloff et al.. January 2000, 30–38.
- One Product, One Process, One Set of Specifications: A Proven Quality Paradigm for the Safety and Efficacy of Biologic Drugs. T. Copmann et al.. March 2001, 14–24.
- Do Not Pass Go, Do Not Collect 2,000 ECUs: The European Union’s Centralized Procedure. A. Bowers S. Hunter, and N. Chew. March 2000, 28–38.
- Asilomar 2000: Symposium on Science, Ethics, and Society. C. Scott. March 2000, 10–14.
- Announcing USP Chapter <1046>, ‘Cell and Gene Therapy Products’. S. Seaver. January 2000, 26–29.
- BIO Business Performance, Not Promises: Performance, Not Promises. C.B. Feldbaum. June 2001, 20–24.
- Preparation and Qualification of Certified Reference Materials and Working Standards. L. Huber. June 1999, 84.
- Generic Biologics: Notes from the Path Less Traveled. B. Zeid. March 1999, 24–32.
- Qualification of UV-Visible Spectrophotometers — Practical Implementation. T. Owen. January 1999, 62–66, 25.
- Stepwise Implementation of CGMPs: A “GSP” Approach. L.E. Little. September 1998, 37–41.
- BIOTECHNOLITICS: An Entrepreneur’s Political Agenda. C.B. Feldbaum. June 1998, 8–11.
- BioRegion: Using a Virtual Enterprise to Foster a Regional Biotech Industry. U. Jensen. May 1998, 20–21.
- Assessment of Risk of Bovine Spongiform Encephalopathy in Pharmaceutical Products, Part 2: Example Risk Assessment for a Hypothetical Product. Pharmaceutical Research and Manufacturers of America BSE Committee. March 1998, 18–30.
- Assessment of Risk of Bovine Spongiform Encephalopathy in Pharmaceutical Products, Part 1. Pharmaceutical Research and Manufacturers of America BSE Committee. January 1998, 20–31.
- Facility Qualification Studies. C. DeSain and C. Sutton. January 1998, 38–41.
- Patenting Issues in Functional Genomics. C.R. Sutton. January 1998, 42–44.
- A Tale of Two Meetings. W.R. Tolbert. September 1997, 14–15.
- A Virtual Roundtable. S.A. Montgomery D. Wendt, and C. Scott. September 1997, 32–42.
- Taking the Industry Into the Future: One Day At a Time. C. Scott. September 1997, 44–49.
- Human Genome Initiative**
See Government Policies.
- Human Immunodeficiency Virus (HIV)**
See Education and Training.
- HVAC Systems**
See Controlled Environment.
- Image Analysis**
See Analytical Techniques.
- Immobilized Cell Culture**
Assessing a Disposable Bioreactor for Attachment-Dependent Cell Cultures. P.K. Namdev and P. Lio. February 2000, 44–50.
- Inactivation**
See Downstream Processing.
- Inclusion Bodies**
See Posttranslational Processing.
- Intellectual Property Rights**
Defining Your GMP Training Program with a Training Procedure. J.L. Vesper. November 2000, 28–32.
- Client Confidentiality and Intellectual Property: Key Challenges in Outsourcing. M. Renn K. Hall, and C. Younger. November 2000,

52–54.

- Generic Biologics: Notes from the Path Less Traveled. B. Zeid. March 1999, 24–32.
- Outsourcing Biopharmaceutical Manufacturing Operations. S.H. Messing. June 1998, 28–30.
- Patenting Issues in Functional Genomics. C.R. Sutton. January 1998, 42–44.
- U.S. University Technology Transfer Offices: Finding Them on the World Wide Web. S.W. Compton. July 1997, 26–27.
- U.S. Government Technology Transfer Resources on the World Wide Web. S.W. Compton. September 1997, 58–59.
- Speculating on the Future Patentability of Genomic Data. C.R. Sutton. January 1997, 54–57.
- Regional Technical Assistance and Business Development Programs. S. Compton. July 1998, 10–12,45.

International Business

- GMP, Compliance, and Regulatory Resources on the Worldwide Web: An Update. C. Scott and P.L. Cass. October 2000, 58–62.
- Implementing the Biological Weapons Convention Protocol in the United States: What It Means to the Biopharmaceutical Industry. L.C. Klotz et al.. August 2000, 46–48.
- Successful Technology Transfer: Lessons from Experience. C.J. Dale. October 2000, 48–56.
- Do Not Pass Go, Do Not Collect 2,000 ECUs: The European Union's Centralized Procedure. A. Bowers S. Hunter, and N. Chew. March 2000, 28–38.
- Harmonizing Validation Processes - Beyond Common Goals. R. Price. August 1999, 14–16.
- Maturing Biomanufacturing Industry Offers Sponsors Clear Choices and Benefits. H.L. Levine and J.C. Miller. May 1999, 62–64.
- BIO Business Performance, Not Promises: Performance, Not Promises. C.B. Feldbaum. June 2001, 20–24.
- Qualification of UV-Visible Spectrophotometers — Practical Implementation. T. Owen. January 1999, 62–66,25.
- World AIDS Conference. C. Peterson. August 1999, 16–17.
- BioRegion: Using a Virtual Enterprise to Foster a Regional Biotech Industry. U. Jensen. May 1998, 20–21.
- Snapshots of the Biopharmaceutical Industry in Baden-Württemberg. S.A. Montgomery. May 1998, 22–23.
- Assessment of Risk of Bovine Spongiform Encephalopathy in Pharmaceutical Products, Part 2: Example Risk Assessment for a Hypothetical Product. Pharmaceutical Research and Manufacturers of America BSE Committee. March 1998, 18–30.
- Assessment of Risk of Bovine Spongiform Encephalopathy in Pharmaceutical Products, Part 1. Pharmaceutical Research and Manufacturers of America BSE Committee.

January 1998, 20–31.

- Partnering for the Future: U.S. Biotechnology Companies Find Business Allies in Europe. R.S. Esposito. October 1997, 24–28.
- Holland: A Gateway for Biopharmaceutical Companies. W. Schless. June 1997, 14–18.

Investigational New Drug Applications

- Practices and Considerations in the Development of an Allogeneic Cellular Transplant. H.M. Nugent A.M. Woodland, and D. Deane. January 2001, 36–41.
- Comparability Analysis to Support a Manufacturing Site Change and Process Modifications for a Biopharmaceutical: A Regulatory Submission Case Study. T.L. Talarico et al.. January 1999, 42–47.

Legal Issues

- Generic Biologics: Notes from the Path Less Traveled. B. Zeid. March 1999, 24–32.
- BIOtechnopolitics: An Entrepreneur's Political Agenda. C.B. Feldbaum. June 1998, 8–11.
- Patenting Issues in Functional Genomics. C.R. Sutton. January 1998, 42–44.
- Speculating on the Future Patentability of Genomic Data. C.R. Sutton. January 1997, 54–57.
- The IRS and the Independent Contractor: Knowing the Rules of the Game. A.E. Schultz. July 2001, 24–26,70.

Legislation

See Government Policies.

Lipids

See Drug Formulation and Delivery.

Liposomes

See Drug Formulation and Delivery.

Liquid-Liquid Partitioning

See Downstream Processing.

Mammalian Cell Culture

- Pharmaceutical Companies Provide Unique Contract Service Capabilities. S. Fox. July 2000, 30–34.
- Assessing a Disposable Bioreactor for Attachment-Dependent Cell Cultures. P.K. Namdev and P. Lio. February 2000, 44–50.
- Tutorial: Examining the Relationship Between Media and Light. W.H. Siegel. January 2000, 65–66.
- Resistance of Porcine Circovirus to Gamma Irradiation. Z.M. Plavsic and S. Bolin. April 2001, 32–36.
- Detection of Microbial Contamination in Cell Cultures Using a Laser Scanning System. A.O. Onadipe. April 2001, 38–40.
- Some Methods for Contamination Testing of a Master Cell Bank. M.d.R. Alemán et al.. June 2000, 48–52.
- Replacing the Animal Component in Serum: Evaluating Raw Materials for Inclusion in Optimized Hybridoma Media. S.C. Peppers

et al.. May 2001, 22–30.

- Transgenic Protein Production: The Technology and Major Players. P. Rohricht. March 1999, 46–48.
- The Basics of Laboratory-Scale Mammalian Cell Cryopreservation. L. Wolfenbarger. October 1998, 35–39.
- Large-Scale Production of a Monoclonal IgM in a Hybridoma Suspension Culture. M.A. Cacciuto et al.. April 1998, 20–27.
- Using an External Vortex Flow Filtration Device for Perfusion Cell Culture. J.I. Horvitz et al.. October 1997, 30–35.
- Production-Scale Qualification of a Novel Cell Culture Medium Format. R. Radominski et al.. July 2001, 34–39.

Managing Your Career Columns

- "Outside Looking In" in Managing Your Career. D.G. Jensen. November 2000, 68–70.
- "In Pursuit of a Goal" in Managing Your Career. D.G. Jensen. March 2001, 54–56.
- Rejecting Pareto. D.G. Jensen. October 2000, 78–80.
- The Cover Letter — Door Opener Par Excellence. D.G. Jensen. September 2000, 70–71.
- Revisiting the Resume. D.G. Jensen. July 2000, 71–72.
- Managing Your Career: Dirty Tricks and Sneaky Business. D.G. Jensen. June 2000, 65–66.
- Twenty Minutes a Day to a New Job. D.G. Jensen. May 2000, 62–63.
- A Monster of a Slump. D.G. Jensen. April 2000, 58–59.
- The Agony and the Ecstasy of the Job Search. D.G. Jensen. March 2000, 58–59.
- "Discussing Your Weaknesses" in Managing Your Career. D.G. Jensen. April 2001, 51–52.
- Motivating Innovators. D.G. Jensen. January 2001, 50–51.
- Getting Yourself Out There. D.G. Jensen. August 2000, 69–70.
- "Become a People Magnet, Part 2" in Managing Your Career. D.G. Jensen. January 2000, 60–62.
- Become a People Magnet, Part 1. D.G. Jensen. November 1999, 63–64.
- "Time and How We Waste It" in Managing Your Career. D.G. Jensen. May 2001, 66–68.
- "How to Win at Dogs and Ponies" in Managing Your Career. D.G. Jensen. September 1999, 59–60.
- Who's In Charge?: Five Keys to Your Career Destiny. D.G. Jensen. August 1999, 50–51.
- Is Your Career Ready for the Next Millennium?. D.G. Jensen. June 1999, 64–66.
- The Final Cut. D.G. Jensen. May 1999, 65–66.
- "Want to Be Headhunted?: Part 2, Four Ways to Get a Recruiter's Attention" in Managing Your Career. D.G. Jensen. June 2001, 68–69.
- Leadership Styles '99. D.G. Jensen. April 1999,

44–45.

When Thoughts Become Things: Positive Thinking or Positive Focusing?. D.G. Jensen. March 1999, 61–62.

Rules of the Road: (Previously) Unwritten Rules of Success for Bio Careers. D.G. Jensen. January 1999, 56–57.

Winning the Good Battle. D.G. Jensen. November 1998, 54,63.

Quantum Leaders at Work. D.G. Jensen. October 1998, 48,56.

The Job Seeker's Moments of Truth. . September 1998, 50–51.

Underemployment: Following the Path of Least Resistance. D.G. Jensen. June 1998, 68–69.

30 Ways to Court Lady Luck. D.G. Jensen. May 1998, 96–97,100.

Anatomy of a Search. D.G. Jensen. April 1998, 52–53.

Your Career - Pearls or Pinecones? (Part 2). D.G. Jensen. March 1998, 50–51.

It's Quitting Time. D.G. Jensen. January 1998, 50–51.

Your Career: Pearls or Pinecones? (Part 1). D.G. Jensen. November 1997, 64–65.

The Email Revolution. D.G. Jensen. October 1997, 56–57.

The Killer Instinct: Getting Things Done Despite the Odds. D.G. Jensen. September 1997, 69–71.

Birkenstocks or White Shirts?. D.G. Jensen. June 1997, 65–66.

"There Is No Stability" in Managing Your Career. D.G. Jensen. May 1997, 88,98.

Persistence and Optimism Rule the Job Search. D.G. Jensen. April 1997, 71–72.

Choosing a Winner: The Art of Interviewing. D.G. Jensen. March 1997, 52–53.

Three Immutable Laws of Networking. D.G. Jensen. January 1997, 58–59.

Not a Natural Born Leader?. D.G. Jensen. July 2001, 52–54.

Master Files

Master Planning and Validation: Part 1: Anatomy of a Validation Master Plan. J. Agaloco. March 2000, 40–44.

Media

Tutorial: Examining the Relationship Between Media and Light. W.H. Siegel. January 2000, 65–66.

Replacing the Animal Component in Serum: Evaluating Raw Materials for Inclusion in Optimized Hybridoma Media. S.C. Peppers et al.. May 2001, 22–30.

Production-Scale Qualification of a Novel Cell Culture Medium Format. R. Radominski et al.. July 2001, 34–39.

Microbial Fermentation

Pharmaceutical Companies Provide Unique Contract Service Capabilities. S. Fox. July 2000, 30–34.

The Squeeze in Contract Biomanufacturing. R. Lias and S. Fogerty. July 2001, 18–22.

20 Tips for Purchasing Research Fermentors and Bioreactors: A Practical Guide for Researchers, Part 2. J. Cino and S. Frey. February 1997, 42–48.

Microcarriers

See *Mammalian Cell Culture*.

Monoclonal Antibodies

Spectroscopic Determination of Chelator Content in Antibody–Chelator Conjugates: UV-Vis, Fluorescence, and MALDI-TOF MS Studies. E. Dadachova. November 2000, 40–44.

Corn Seed Production of Therapeutic Proteins Moves Forward: One Company's Experience. J. Baez D. Russell, and J. Craig. August 2000, 50–54.

Immunogenicity:: The Last Hurdle for Clinically Successful Therapeutic Antibodies. F. Adair. October 2000, 42–46.

Encapsulated Antibody-Producing Cells for Long-Term Passive Immunotherapy. M. Pelegrin et al.. October 1999, 32–35.

Viral Clearance Strategies for Biopharmaceutical Safety: Part 3: A Multifaceted Approach to Process Validation. S. Forbes and H. Aranha. May 2001, 42–54,90.

Replacing the Animal Component in Serum: Evaluating Raw Materials for Inclusion in Optimized Hybridoma Media. S.C. Peppers et al.. May 2001, 22–30.

The Squeeze in Contract Biomanufacturing. R. Lias and S. Fogerty. July 2001, 18–22.

Trangenics Go Commercial. M. Young et al.. July 1998, 24–28.

Production of Biopharmaceutical Proteins in the Milk of Transgenic Dairy Animals. M.W. Young. June 1997, 34–38.

Comparability (Bioequivalence) Testing of Monoclonal Antibodies. M.A. Schenerman and K. Phillips. April 1997, 20–26,72.

Monoclonal Antibody Recovery

See *Protein/Polypeptide Recovery*.

New Drug Applications

The FDA Regulatory Methods Validation Program for NDAs and ANDAs. T. Layloff et al.. January 2000, 30–38.

One Product, One Process, One Set of Specifications: A Proven Quality Paradigm for the Safety and Efficacy of Biologic Drugs. T. Copmann et al.. March 2001, 14–24.

The Elimination of Environmental Assessments for Biologically Derived Drug Products. T.J. Malott. September 1997, 50–54.

Oligonucleotides

Reviewing Antisense Oligonucleotide Therapy: Part 2, Delivery Issues. S.K. Das and K.J. Miller. November 1999, 44–51.

Reviewing Antisense Oligonucleotide Therapy, Part 1: Action and Design. S.K. Das and K.J. Miller. October 1999, 42–48.

Nonviral Gene Delivery Systems: Part 2, Physical Characterization. T.J. Anchordocuy.

September 1999, 46–51.

Nucleic Acid Drug Delivery, Part 2:: Delivery to the Brain. S. Wu-Pong and D.A. Gewirtz. January 1999, 32–36.

Nucleic Acid Drug Delivery, Part 1: Delivery Issues Related to Dividing Cells. S. Wu-Pong and D.A. Gewirtz. November 1998, 28–35.

Orphan Drugs

Patents

See *Intellectual Property Rights*.

Peptide Mapping

See *Analytical Techniques*.

Peptide Synthesis

Personnel Issues

Restrictive Covenants: Protecting Confidential and Proprietary Information. C.A. Amalfe and K.R. Heslin. February 2000, 52–55.

"Want to Be Headhunted?" in Managing Your Career. D.G. Jensen. February 2001, 56–58.

Surveying the Field:Your Career in the Biopharmaceutical Industry. A. Muir. May 1999, 28–36.

Becoming a Good and Valued Client: Dos and Don'ts for a Successful Outsourcing Relationship. R.S. Woodward. June 1998, 44–49.

Demographics of Women in the San Diego Biopharmaceutical Industry. H.A. de Haan. February 1997, 8–10.

Biotechnology and Pharmaceuticals: 10 Years Later. M.D. Dibner. September 1997, 24–30.

Quality Assurance in the Next Millennium. J.R. Christensen. August 1997, 10.

Science or Project Management: What (and Who) is More Important in Biotech?. T. Fitz. July 2001, 28–29.

Plant Biotechnology

Corn Seed Production of Therapeutic Proteins Moves Forward: One Company's Experience. J. Baez D. Russell, and J. Craig. August 2000, 50–54.

The Industrial Production Costs of Recombinant Therapeutic Proteins Expressed in Transgenic Corn. D. Mison and J. Curling. May 2000, 48–54.

Posttranslational Processing

Corn Seed Production of Therapeutic Proteins Moves Forward: One Company's Experience. J. Baez D. Russell, and J. Craig. August 2000, 50–54.

Process Automation

See *Automation*.

Process Control/Monitoring

CGMP Pharmaceutical Scale-Up: Part 4: Installation, Commissioning, Development. C. Pepper M. ,H. Patel ,Hartounian, and H.

Hartounian. February 2000, 28–34.
 Tutorial: The Importance of Time Variables in Temperature Studies. P.A. Hugunin and G. Straub. February 2000, 73–74.
 Making Better Decisions:: Troubleshooting Biopharmaceutical Processes Using Problem Analysis. J.A. Myers. October 2000, 32–35.
 Process Hazard Analysis and Critical Control Point Identification. C. DeSain and C. Sutton. October 2000, 36–40.
 Blow-Fill-Seal Technology: Design Optimization of a Particulate Control System. J. Price. April 1999, 25–29,43.
 Defining Critical Variables in Well-Characterized Biotechnology Processes. R.J. Seely et al.. April 1999, 33–36.
 Setting Biopharmaceutical Specifications. J. Cohen and M. Busch. August 1998, 38–42.
 Large-Scale Production of a Monoclonal IgM in a Hybridoma Suspension Culture. M.A. Cacciuttolo et al.. April 1998, 20–27.
 20 Tips for Purchasing Research Fermentors and Bioreactors: A Practical Guide for Researchers, Part 2. J. Cino and S. Frey. February 1997, 42–48.
 In-Process Control for Large-Scale Animal Cell Culture. G. MacMichael. March 1997, 38–40.
 Avoiding Instrument-Associated Aberrations in Purification Scale-Up and Scale-Down. P. Gagnon. March 1997, 42–45.

Products and Marketing

Biotechnology and Pharmaceuticals: 10 Years Later. M.D. Dibner. September 1997, 24–30.
 Viewpoint: Addressing the New Bottleneck. P. Fernandex. July 2001, 14–15.

Professional Societies/Associations

Protein Denaturation

See *Downstream Processing*.

Protein Folding

See *Posttranslational Processing*.

Protein/Polypeptide Recovery

Transgenic Protein Production: Part 3, Nuclear Transfer Technology. P. Rohricht and D. Ayares. November 1999, 56–60.
 Pichia pastoris: A Eukaryotic System for the Large-Scale Production of Biopharmaceuticals. C. Dale A. Allen, and S. Fogerty. November 1999, 36–42.
 Demonstrating Process Robustness for Chromatographic Purification of a Recombinant Protein. B.D. Kelley et al.. October 1997, 36–47.

Protein Precipitation

See *Posttranslational Processing*.

Protein Sequencing

Public Policy

Purified Water

See *Water Systems*.

QA/QC

Performance: The Goal of Training: or Why Training Is Not Always the Answer February 2001, 44–46.
 Spectroscopic Determination of Chelator Content in Antibody–Chelator Conjugates: UV-Vis, Fluorescence, and MALDI-TOF MS Studies. E. Dadachova. November 2000, 40–44.
 Improving the ESD Procedure for Outlier Testing. M.A. Djauhari. March 2001, 42–46.
 Evaluation of Two Bovine Cell Lines as Hosts for Detecting Several Common Bovine Viruses in Fetal Bovine Serum. Z.M. Plavsic. September 2000, 48–51.
 Demonstrating Product Comparability. H.K.B. Simmerman. September 2000, 58–62.
 Meeting the Challenges of Enzyme Assay Validation. U. Patel. July 2000, 48–52.
 Two Statistical Methods for Estimating Relative Potency of Bioassays. R. Reeve. July 2000, 54–60.
 Tutorial: Exploiting the Poisson Distribution for Bioburden Investigations. D.W. Cooper. April 2000, 65–66.
 Regulatory Requirements for Somatic Cell Therapy Products:: Safety Concerns and Practical Solutions. M.S. Lao. March 2000, 50–55.
 Tutorial: The Importance of Time Variables in Temperature Studies. P.A. Hugunin and G. Straub. February 2000, 73–74.
 The Quality Agreement: Compliance Considerations in Selecting a Contract Manufacturer. G. Bobrowics. February 2001, 14–20.
 A Guide to Determining Sample Sizes and Outlier Criteria in Analytical Investigations. J.D. Hofer and E.C. Rickard. May 2001, 32–41,68.
 Minimizing Risks from Chromatography Media: Management of Raw Materials in Biopharmaceutical Production. R.M. Kennedy and L. Gonzales. May 2001, 56–58.
 A Practical Approach to Investigating GMP Failures. J.F. Huzsoll. August 1999, 39–42.
 FDA and the Promise of FDAMA. L.A. Suydam. August 1999, 43–45.
 Bioburden Determinations: Most Probable Number or Colony Counting?. D.W. Cooper. June 1999, 53–55,90.
 Technical Note:: An Exact Test for Outlier Detection. M.A. Djauhari. June 1999, 56–59.
 Cancer Gene Therapy Using Plasmid DNA: Pharmacokinetics and Safety Evaluation of an IL-2 Plasmid DNA Expression Vector in Rodents and Nonhuman Primates. S.E. Parker et al.. April 1999, 18–23.
 In Search of Standardized Definitions for Validation, Qualification, Verification, and Calibration. L. Huber. April 1999, 56–58.
 Validating Computer Systems for Clinical Trials: Part 1, Leveraging Your Supplier's Verification Efforts. G. Benghiat A. Miller, and P. Bleicher. January 1999, 39–41.
 Comparability Analysis to Support a Manufacturing Site Change and Process Modifications for a Biopharmaceutical: A Regulatory Submission Case Study. T.L. Talarico et al.. January 1999, 42–47.
 Replacing Slab Gel Electrophoresis Methods with Capillary Electrophoresis for Quality Control and Stability Testing. S.H. Bowen and M.A. Schenerman. November 1998, 42–46,50.
 Validating a Refrigerator-Freezer. P.A. Cloud. November 1998, 47–50.
 Responding to FDA-483s and Warning Letters. D.L. Chesney and A.E. Kelley. October 1998, 26–29.
 Stepwise Implementation of CGMPs: A "GSP" Approach. L.E. Little. September 1998, 37–41.
 Ensuring Laboratory Compliance. R.H. Johnson. August 1998, 30–32.
 GMP Compliance from a Production Manager's Point of View. M. Pemberton. August 1998, 34–37.
 The Nuts and Bolts of FDA Inspections: Before, During, and After. J.R. Christensen. August 1998, 44–46.
 Beating the Documentation Blues. B.K. Immel. August 1998, 47–51.
 Learning from Bioburden Count Distributions. D.W. Cooper. March 1998, 32–37.
 Facility Qualification Studies. C. DeSain and C. Sutton. January 1998, 38–41.
 Validating a Laboratory Incubator. P.A. Cloud. November 1997, 30,39–42.
 Big Biotech: Designing the Plant of the Future. R.L. Williams. November 1997, 44–51.
 The Future of Quality Control for Gene and Cell Therapies. S.S. Kuwahara. September 1997, 64–65.
 Current Trends: Impact of the Well-Characterized Regulatory Paradigm. L. Little. August 1997, 8–9,12,58.
 Quality Assurance in the Next Millennium. J.R. Christensen. August 1997, 10.
 Safety Considerations and Quality Assurance for Xenotransplantation. L.J. Schiff. August 1997, 48–50.
 Calibration and Validation of UV-Vis Absorption Spectrophotometers. A.C. Richardson and J.D. Messman. August 1997, 7.
 Before You Sign the Contract: Evaluating the Level of CRO Client Service. R.S. Woodward. June 1997, 26–32.
 Characterization of Plasmid DNA Vectors for Use in Human Gene Therapy, Part 2. M. Marquet N.A. Horn, and J.A. Meek. June 1997, 40–45.
 Complete Automation of the Bacterial Endotoxin Assay. K.L. Williams. June 1997, 46–57.
 Characterization of Plasmid DNA Vectors for Use in Human Gene Therapy, Part 1. M. Marquet N.A. Horn, and J.A. Meek. May 1997, 42–50.

Quality Control for Ex Vivo Cell Therapy. G. Kielpinski et al.. January 1997, 34–40.

Regulatory Affairs Columns

Gene Therapy, Birth to Adolescence. N.J. Chew. September 2000, 36–39.

Cell and Tissue Therapies: Working with Complex, Mutable, Living Entities. N. Chew. April 2001, 20–24.

ICH Regulatory Communications. J. Burley and N.J. Chew. September 1999, 20–24,60.

Harmonizing the Validation of Analytical Procedures. N.J. Chew and E. Wiechert. August 1999, 18–24, 51.

ICH Now: Harmony at the End of the Century. N.J. Chew. June 1999, 24–32.

Global Drug Development: Singing from the Same Songbook. N.J. Chew. May 1999, 18–26.

The Fast Track to Market. N.J. Chew. March 1999, 14–18.

1998: That Was the Year That Was. N.J. Chew. January 1999, 20–25.

Right from the Start: Conducting Clinical Trials That Succeed. T. Seeger and N.J. Chew. October 1998, 20–24.

Xenotransplantation: Science, Regulation, and Ethics. N.J. Chew. September 1998, 22–26,64.

Reinventing FDA, Part 5: Chemistry, Manufacturing, and Controls. J. Morgan and N.J. Chew. June 1998, 12–16,71.

Reinventing FDA, Part 4: Gene, Cell, and Tissue Therapies. N.J. Chew. May 1998, 44–51.

Reinventing FDA, Part 3: Postapproval Changes. J. Morgan and N.J. Chew. April 1998, 16–18,56.

Reinventing FDA, Part 2: Overcoming the Paper Tiger. N.J. Chew J. Morgan, and C. Wantowsk. January 1998, 14–19.

Reinventing FDA, Part 1: Federal Rulemaking. N.J. Chew. November 1997, 22–29.

Agony and Ecstasy in Biopharmaceutical Regulation. N.J. Chew. September 1997, 20–23.

Defining Good Regulatory Practices. N.J. Chew. May 1997, 38–40.

1996 in Review. N.J. Chew. March 1997, 16–24.

Registration of Biotech Products in the EU. J.C. Warwick D.T. Wright, and N.J. Chew. January 1997, 28–32.

Regulatory Issues

A Case Study in Compliance: Supporting 21 CFR Part 11 with a UV-Vis System. S. Bayerbach. November 2000, 48–50.

Preparing for Electronic Records and Electronic Signatures. M.L. Wyrick. November 2000, 10–12.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 2: Security Aspects for Systems and Applications. W. Winter and L. Huber. November 2000, 18–23.

Implementing 21 CFR Part 11 in Analytical

Laboratories: Part 3: Ensuring Data Integrity in Electronic Records. W. Winter and L. Huber. November 2000, 24–27.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 4: Data Migration and Long-Term Archiving for Ready Retrieval. W. Winter and L. Huber. November 2000, 28–33.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 6: Biometric Identification — Limits and Possibilities. W. Winter and L. Huber. November 2000, 40–43.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 7: Making Legacy Systems Compliant. C. Nickel W. Winter, and L. Huber. November 2000, 44–47.

Defining Your GMP Training Program with a Training Procedure. J.L. Vesper. November 2000, 28–32.

Biopharmaceutical Shipping: Moving at the Speed of Life. J. Johnson. March 2001, 34–36.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 3: Ensuring Data Integrity in Electronic Records. W. Winter and L. Huber. March 2000, 45–49.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 1: Overview and Requirements. W. Winter and L. Huber. November 2000, 14–17.

The Rule: Part 11 — Electronic Records; Electronic Signatures. . November 2000, 62–64.

Inactivation of Several Bovine Viruses in Fetal Bovine Serum Using pH Adjustments. . November 2000, 34–38.

GMP, Compliance, and Regulatory Resources on the Worldwide Web:: An Update. C. Scott and P.L. Cass. October 2000,58–62.

Comparing the Safety of Synthetic and Biological Ligands Used for Purification of Therapeutic Proteins. M. Behizad and J.M. Curling. September 2000, 42–46.

Evaluation of Two Bovine Cell Lines as Hosts for Detecting Several Common Bovine Viruses in Fetal Bovine Serum. Z.M. Plavsic. September 2000, 48–51.

Part 5: The Importance of Instrument Control and Data Acquisition. W. Winter and L. Huber. September 2000, 52–56.

Implementing the Biological Weapons Convention Protocol in the United States: What It Means to the Biopharmaceutical Industry. L.C. Klotz et al.. August 2000, 46–48.

Implementing 21 CFR Part 11 in Analytical Laboratories, Part 4: Data Migration and Long-Term Archiving for Ready Retrieval. L. Huber and W. Winter. June 2000, 58–64.

Regulatory Requirements for Somatic Cell Therapy Products:: Safety Concerns and Practical Solutions. M.S. Lao. March 2000, 50–55.

The FDA Regulatory Methods Validation Program for NDAs and ANDAs. T. Layloff et al.. January 2000, 30–38.

The Quality Agreement: Compliance Consider-

ations in Selecting a Contract Manufacturer. G. Bobrowics. February 2001, 14–20.

One Product, One Process, One Set of Specifications: A Proven Quality Paradigm for the Safety and Efficacy of Biologic Drugs. T. Copmann et al.. March 2001, 14–24.

Project Management of Small R&D Companies, Part 2: Perspectives from a Large CRO. F. Beddia et al.. March 2001, 38–40.

Resistance of Porcine Circovirus to Gamma Irradiation. Z.M. Plavsic and S. Bolin. April 2001, 32–36.

Project Management of Small R&D Companies, Part 1: Perspective from a Large CRO. F. Beddia et al.. February 2001, 26–28.

Viral Clearance Strategies for Biopharmaceutical Safety: Part 1, General Considerations. H. Aranha. January 2001, 28–35.

Viewpoint: Electronic Submissions — Faster Assembly and Review. . January 2001, 12–16.

From R&D to Licensing: What to Do and When to Do It. . January 2001, 18–27.

Practices and Considerations in the Development of an Allogeneic Cellular Transplant. H.M. Nugent A.M. Woodland, and D. Deane. January 2001, 36–41.

Process Hazard Analysis and Critical Control Point Identification. C. DeSain and C. Sutton. October 2000, 36–40.

A Brief History of the GMPs: The Power of Storytelling. B.K. Immel. August 2000, 26–36.

When Things Go Wrong, Part 1: The Consequences of Noncompliance. B.K. Immel. August 2000, 38–44.

Do Not Pass Go, Do Not Collect 2,000 ECUs: The European Union's Centralized Procedure. A. Bowers S. Hunter, and N. Chew. March 2000, 28–38.

Implementing 21 CFR Part 11 in Analytical Laboratories: Part 2, Security Aspects for Systems and Applications. W. Winter and L. Huber. January 2000, 44–50.

Announcing USP Chapter <1046>, 'Cell and Gene Therapy Products'. S. Seaver. January 2000, 26–29.

Revisiting Validation: Continuing Concerns, New Challenges. G. Sofer. October 1999, 26–30.

Viral Clearance Strategies for Biopharmaceutical Safety: Part 3: A Multifaceted Approach to Process Validation. S. Forbes and H. Aranha. May 2001, 42–54,90.

A Guide to Determining Sample Sizes and Outlier Criteria in Analytical Investigations. J.D. Hofer and E.C. Rickard. May 2001, 32–41,68.

The Reemergence of the Biopharmaceutical Contract Manufacturing Industry. R.L. McKown. May 1999, 54–57.

The Compliance Costs of Hasty Process Development. G. Bobrowicz. August 1999, 35–38.

A Practical Approach to Investigating GMP Failures. J.F. Huzsoll. August 1999, 39–42.

FDA and the Promise of FDAMA. L.A. Suydam.

- August 1999, 43–45.
- GMP, Compliance, and Regulatory Resources Shine on the Worldwide Web. C. Scott. August 1999, 46–48.
- Harmonizing Validation Processes - Beyond Common Goals. R. Price. August 1999, 14–16.
- BIO Business Performance, Not Promises: Performance, Not Promises. C.B. Feldbaum. June 2001, 20–24.
- Defining Critical Variables in Well-Characterized Biotechnology Processes. R.J. Seely et al.. April 1999, 33–36.
- Generic Biologics: Notes from the Path Less Traveled. B. Zeid. March 1999, 24–32.
- Validating Computer Systems for Clinical Trials: Part 1, Leveraging Your Supplier's Verification Efforts. G. Benghiat A. Miller, and P. Bleicher. January 1999, 39–41.
- Comparability Analysis to Support a Manufacturing Site Change and Process Modifications for a Biopharmaceutical: A Regulatory Submission Case Study. T.L. Talarico et al.. January 1999, 42–47.
- Cell Bank Validation: Comparing Points to Consider and ICH Guidelines. M.S. Lao. January 1999, 48–51.
- Qualification of UV-Visible Spectrophotometers — Practical Implementation. T. Owen. January 1999, 62–66, 25.
- Responding to FDA-483s and Warning Letters. D.L. Chesney and A.E. Kelley. October 1998, 26–29.
- Combining ELISA, RP-HPLC, and SDS-PAGE to Define the Potency of a Complex Biologic. J.R. Zabrecky et al.. October 1998, 30–34.
- Stepwise Implementation of CGMPs: A "GSP" Approach. L.E. Little. September 1998, 37–41.
- Ensuring Laboratory Compliance. R.H. Johnson. August 1998, 30–32.
- The Nuts and Bolts of FDA Inspections: Before, During, and After. J.R. Christensen. August 1998, 44–46.
- Regulatory Aspects of Column Chromatography in Biopharmaceutical Manufacturing: U.S. and EU Regulatory Attitudes Toward Change. M. Behizad and D. Baines. May 1998, 72–82.
- A Bovine Spongiform Encephalopathy Validation Study for Aprotinin and Bovine Serum Albumin. M. Blum et al.. April 1998, 28–34.
- Assessment of Risk of Bovine Spongiform Encephalopathy in Pharmaceutical Products, Part 2: Example Risk Assessment for a Hypothetical Product. Pharmaceutical Research and Manufacturers of America BSE Committee. March 1998, 18–30.
- Assessment of Risk of Bovine Spongiform Encephalopathy in Pharmaceutical Products, Part 1. Pharmaceutical Research and Manufacturers of America BSE Committee. January 1998, 20–31.
- Biotechnology and Pharmaceuticals: 10 Years Later. M.D. Dibner. September 1997, 24–30.
- A Tale of Two Meetings. W.R. Tolbert. September 1997, 14–15.
- The Elimination of Environmental Assessments for Biologically Derived Drug Products. T.J. Malott. September 1997, 50–54.
- Current Trends: Impact of the Well-Characterized Regulatory Paradigm. L. Little. August 1997, 8–9, 12, 58.
- In-House Development and Validation of Analytical Methods Standards for Biologics: Technical and Regulatory Concerns. W.J. White, Jr. S. Sutton-Jones, and C. Medina. August 1997, 20–24.
- Safety Considerations and Quality Assurance for Xenotransplantation. L.J. Schiff. August 1997, 48–50.
- Comparability (Bioequivalence) Testing of Monoclonal Antibodies. M.A. Schenerman and K. Phillips. April 1997, 20–26, 72.
- An Immuno-Ligand Assay for the Detection and Quantitation of Contaminating Proteins in Recombinant Human Erythropoietin (r-HuEPO). I.A. Ghobrial D.T. Wong, and B.G. Sharma. January 1997, 42–45.
- The IRS and the Independent Contractor: Knowing the Rules of the Game. A.E. Schultz. July 2001, 24–26, 70.
- Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products: Highlights from the New PDA Technical Report No. 34. R.E. Madsen. July 2001, 30–32.
- Scale-Up Strategies**
- CGMP Pharmaceutical Scale-Up: Part 4: Installation, Commissioning, Development. C. Pepper M. ,H. Patel ,Hartounian, and H. Hartounian. February 2000, 28–34.
- The Industrial Production Costs of Recombinant Therapeutic Proteins Expressed in Transgenic Corn. D. Mison and J. Curling. May 2000, 48–54.
- Project Management of Small R&D Companies, Part 2: Perspectives from a Large CRO. F. Beddia et al.. March 2001, 38–40.
- Project Management of Small R&D Companies, Part 1: Perspective from a Large CRO. F. Beddia et al.. February 2001, 26–28.
- Customized Ligands Optimize Affinity Chromatography Procedures. L-J Larsson. January 2001, 42–44.
- Planning Ahead for Manufacturing Facility Changes: A Case Study in Outsourcing. M. Katz. January 2001, 46–47.
- Pichia pastoris*: A Eukaryotic System for the Large-Scale Production of Biopharmaceuticals. C. Dale A. Allen, and S. Fogerty. November 1999, 36–42.
- CGMP Pharmaceutical Scale-Up: Part 1: Design. C. Pepper M. Patel, and H. Hartounian. September 1999, 26–34.
- Ion-Exchange Displacement Chromatography: Scale-Up and Displacer Clearance for rHuBDNF. K.A. Barnthouse et al.. September 1999, 35–44.
- Transgenic Protein Production: Part 2, Process Economics. P. Rohricht. September 1999, 52–54.
- Nonviral Gene Delivery Systems, Part 1: Physical Stability. T.J. Anchordoquy. June 1999, 42–48.
- Transgenic Protein Production: The Technology and Major Players. P. Rohricht. March 1999, 46–48.
- Trangenics Go Commercial. M. Young et al.. July 1998, 24–28.
- Large-Scale Cryopreservation of Cells, Cell Components, and Biological Solutions. R. Wisniewski. September 1998, 42–49, 61.
- Elements of Downstream Bioprocess Validation. N.M. Lugo. June 1998, 18–26.
- Outsourcing Biopharmaceutical Manufacturing Operations. S.H. Messing. June 1998, 28–30.
- Considerations for Selecting a Contract Biomanufacturer. D.M. Rehkop. June 1998, 32–34.
- Developing Large-Scale Cryopreservation Systems for Biopharmaceutical Products. Richard Wisniewski. June 1998, 50–60.
- Comparative Performances of 70 Ion-Exchange Chromatography Sorbents for Purification of Biomolecules. J. Dennis P. Levison, and C. Mumford. April 1998, 44–50.
- Big Biotech: Designing the Plant of the Future. R.L. Williams. November 1997, 44–51.
- Production of Biopharmaceutical Proteins in the Milk of Transgenic Dairy Animals. M.W. Young. June 1997, 34–38.
- Avoiding Instrument-Associated Aberrations in Purification Scale-Up and Scale-Down. P. Gagnon. March 1997, 42–45.
- The Squeeze in Contract Biomanufacturing. R. Lias and S. Fogerty. July 2001, 18–22.
- Separation and Purification**
- Comparing the Safety of Synthetic and Biological Ligands Used for Purification of Therapeutic Proteins. M. Behizad and J.M. Curling. September 2000, 42–46.
- The Industrial Production Costs of Recombinant Therapeutic Proteins Expressed in Transgenic Corn. D. Mison and J. Curling. May 2000, 48–54.
- Performance Qualification of Clean-in-Place Systems: Lessons from Experience in Multiproduct Biopharmaceutical Manufacturing. L. Hill. April 2000, 24–29.
- Inactivation of Viruses and Mycoplasmas in Fetal Bovine Serum Using 56 °C Heat. J. Smith M. Plavsic, and D.J. Danner. June 1999, 50–52.
- Bioburden Determinations: Most Probable Number or Colony Counting?. D.W. Cooper. June 1999, 53–55, 90.
- Defining Critical Variables in Well-Characterized Biotechnology Processes. R.J. Seely et al.. April 1999, 33–36.
- The Squeeze in Contract Biomanufacturing. R. Lias and S. Fogerty. July 2001, 18–22.
- Multiuse Chromatography System: A Clean-in-Place Validation Case Study. P.A. Garipey

- R.S. Moore, and G. Sofer. September 1998, 32–36.
- Setting Biopharmaceutical Specifications. J. Cohen and M. Busch. August 1998, 38–42.
- Elements of Downstream Bioprocess Validation. N.M. Lugo. June 1998, 18–26.
- Regulatory Aspects of Column Chromatography in Biopharmaceutical Manufacturing: U.S. and EU Regulatory Attitudes Toward Change. M. Behizad and D. Baines. May 1998, 72–82.
- Comparative Performances of 70 Ion-Exchange Chromatography Sorbents for Purification of Biomolecules. J. Dennis P. Levison, and C. Mumford. April 1998, 44–50.
- Technology Profile: Simulated Moving Bed Technology in the Chiral Separation Process. J. Fireman. July 1997, 22.
- Preparative Purification of Supercoiled Plasmid DNA for Therapeutic Applications. A.P. Green et al.. May 1997, 52–62.
- Displacement Chromatography of Proteins Using Sucrose Octasulfate. S.M. Cramer et al.. May 1997, 64–70, 95.
- Endotoxin Reduction in Macromolecular Solutions: Two Case Studies. S.P. Crump et al.. March 1997, 32–37.
- Avoiding Instrument-Associated Aberrations in Purification Scale-Up and Scale-Down. P. Gagnon. March 1997, 42–45.
- The Role of Charge in the Retention of DNA by Charged Cellulose-Based Depth Filters. N. Dorsey J. Eschrich, and G. Cyr. January 1997, 46–49.
- Sera and Serum Substitutes**
See Cell Growth and Viability.
- Standard Operating Procedures**
- Qualifying High-Performance Capillary Electrophoresis Systems. G.A. Ross. November 1999, 81–82.
- Qualifying High-Performance Liquid Chromatography/Mass Spectrometry Systems. W.P. Duncan. October 1999, 65–66.
- Validating Critical Reagents Used in CGMP Analytical Testing: Ensuring Method Integrity and Reliable Assay Performance. N. Ritter and M. Wiebe. May 2001, 12–21.
- Beating the Documentation Blues. B.K. Immel. August 1998, 47–51.
- State Legislation**
See Government Policies.
- Utility Design**
- Vaccines**
- Validation**
- Preparing for Electronic Records and Electronic Signatures. M.L. Wyrick. November 2000, 10–12.
- Implementing 21 CFR Part 11 in Analytical Laboratories: Part 2: Security Aspects for Systems and Applications. W. Winter and L. Huber. November 2000, 18–23.
- Implementing 21 CFR Part 11 in Analytical Laboratories: Part 3: Ensuring Data Integrity in Electronic Records. W. Winter and L. Huber. November 2000, 24–27.
- Implementing 21 CFR Part 11 in Analytical Laboratories: Part 4: Data Migration and Long-Term Archiving for Ready Retrieval. W. Winter and L. Huber. November 2000, 28–33.
- Implementing 21 CFR Part 11 in Analytical Laboratories: Part 5: The Importance of Instrument Control and Data Acquisition. W. Winter and L. Huber. November 2000, 34–38.
- Implementing 21 CFR Part 11 in Analytical Laboratories: Part 6: Biometric Identification — Limits and Possibilities. W. Winter and L. Huber. November 2000, 40–43.
- Implementing 21 CFR Part 11 in Analytical Laboratories: Part 7: Making Legacy Systems Compliant. C. Nickel W. Winter, and L. Huber. November 2000, 44–47.
- Intentionally Degrading Protein Pharmaceuticals to Validate Stability-Indicating Analytical Methods. J. Yu. November 2000, 46–50.
- Ensuring Successful Validation: The Logical Steps to Efficient Cleaning Procedures. G. Amer and P. Deshmane. March 2001, 26–32.
- Implementing 21 CFR Part 11 in Analytical Laboratories: Part 3: Ensuring Data Integrity in Electronic Records. W. Winter and L. Huber. March 2000, 45–49.
- Implementing 21 CFR Part 11 in Analytical Laboratories: Part 1: Overview and Requirements. W. Winter and L. Huber. November 2000, 14–17.
- The Rule: Part 11 — Electronic Records; Electronic Signatures. . November 2000, 62–64.
- GMP, Compliance, and Regulatory Resources on the Worldwide Web.: An Update. C. Scott and P.L. Cass. October 2000, 58–62.
- Part 5: The Importance of Instrument Control and Data Acquisition. W. Winter and L. Huber. September 2000, 52–56.
- Meeting the Challenges of Enzyme Assay Validation. U. Patel. July 2000, 48–52.
- The Evolving Role of Product Characterization During Development. J. Faulkner. June 2000, 26–34.
- Effect of Heat Treatment on Four Viruses Inoculated into BSA and Bovine Transferrin Solution. Z.M. Plavsic. June 2000, 54–56.
- Detecting PEG-rHu MGDF in Rhesus Monkey Serum: An Enzyme-Linked Immunosorbent Assay. D. Chen et al.. April 2000, 48–50.
- Regulatory Requirements for Somatic Cell Therapy Products.: Safety Concerns and Practical Solutions. M.S. Lao. March 2000, 50–55.
- Master Planning and Validation: Part 1: Anatomy of a Validation Master Plan. J. Agalloco. March 2000, 40–44.
- The FDA Regulatory Methods Validation Program for NDAs and ANDAs. T. Layloff et al.. January 2000, 30–38.
- Validation of a Cation-Exchange Method to Test for Residual Amounts of a Cleaning and Sanitizing Solution on Pharmaceutical Process Equipment. M.J. Shifflet and M. Shapiro. January 2000, 51–54.
- Validating the Sanitization of Chromatographic Resins: A Sample Case Study. M. H-S. and C. Broughton. April 2001, 26–30.
- Resistance of Porcine Circovirus to Gamma Irradiation. Z.M. Plavsic and S. Bolin. April 2001, 32–36.
- Detection of Microbial Contamination in Cell Cultures Using a Laser Scanning System. A.O. Onadipe. April 2001, 38–40.
- From R&D to Licensing: What to Do and When to Do It. . January 2001, 18–27.
- Process Hazard Analysis and Critical Control Point Identification. C. DeSain and C. Sutton. October 2000, 36–40.
- Implementing 21 CFR Part 11 in Analytical Laboratories: Part 2, Security Aspects for Systems and Applications. W. Winter and L. Huber. January 2000, 44–50.
- Qualifying High-Performance Capillary Electrophoresis Systems. G.A. Ross. November 1999, 81–82.
- CGMP Pharmaceutical Scale-Up: Part 3: Automation. M Patel C. Pepper, and H. Hartounian. November 1999, 52–54.
- Revisiting Validation: Continuing Concerns, New Challenges. G. Sofer. October 1999, 26–30.
- Qualifying High-Performance Liquid Chromatography/Mass Spectrometry Systems. W.P. Duncan. October 1999, 65–66.
- Validating Critical Reagents Used in CGMP Analytical Testing: Ensuring Method Integrity and Reliable Assay Performance. N. Ritter and M. Wiebe. May 2001, 12–21.
- Viral Clearance Strategies for Biopharmaceutical Safety: Part 3: A Multifaceted Approach to Process Validation. S. Forbes and H. Aranha. May 2001, 42–54, 90.
- Minimizing Risks from Chromatography Media: Management of Raw Materials in Biopharmaceutical Production. R.M. Kennedy and L. Gonzales. May 2001, 56–58.
- Validation of a Chemiluminescent Hybridization Assay for Quantitative Determination of Host Cell DNA in Clarified Conditioned Medium. B. DiPaolo X. Ji, and K. Venkat. May 1999, 38–48.
- The Compliance Costs of Hasty Process Development. G. Bobrowicz. August 1999, 35–38.
- Harmonizing Validation Processes - Beyond Common Goals. R. Price. August 1999, 14–16.
- Inactivation of Viruses and Mycoplasmas in Fetal Bovine Serum Using 56 °C Heat. J. Smith M. Plavsic, and D.J. Danner. June 1999, 50–52.
- Bioburden Determinations: Most Probable Number or Colony Counting?. D.W. Cooper. June 1999, 53–55, 90.

- A Practical Guide to Executing Validation Protocols. G.S. Hodgson. April 1999, 30–32.
- In Search of Standardized Definitions for Validation, Qualification, Verification, and Calibration. L. Huber. April 1999, 56–58.
- Validating Computer Systems for Clinical Trials: Part 2, The Supplier Audit. G. Benghiat A. Miller, and P. Bleicher. March 1999, 51–54.
- Tutorial: Validation of HPLC Methods. L. Huber. March 1999, 64–66.
- Validating Computer Systems for Clinical Trials: Part 1, Leveraging Your Supplier's Verification Efforts. G. Benghiat A. Miller, and P. Bleicher. January 1999, 39–41.
- Cell Bank Validation: Comparing Points to Consider and ICH Guidelines. M.S. Lao. January 1999, 48–51.
- Y2K Bug: A Millennium Debacle. K. Powell-Evans and B. Gibson. July 1998, 14–17, 50.
- The Integration of Design, Construction, and Validation: Solving a Validation Challenge. J.N. Odum. November 1998, 36–41.
- Validating a Refrigerator-Freezer. P.A. Cloud. November 1998, 47–50.
- Validating Computerized Systems Developed Out of House: Reducing the Time It Takes. J. Gottfried. October 1998, 40–43.
- Multiuse Chromatography System: A Clean-in-Place Validation Case Study. P.A. Garipey R.S. Moore, and G. Sofer. September 1998, 32–36.
- Elements of Downstream Bioprocess Validation. N.M. Lugo. June 1998, 18–26.
- A Bovine Spongiform Encephalopathy Validation Study for Aprotinin and Bovine Serum Albumin. M. Blum et al.. April 1998, 28–34.
- Validating a Laboratory Incubator. P.A. Cloud. November 1997, 30, 39–42.
- Demonstrating Process Robustness for Chromatographic Purification of a Recombinant Protein. B.D. Kelley et al.. October 1997, 36–47.
- In-House Development and Validation of Analytical Methods Standards for Biologics: Technical and Regulatory Concerns. W.J. White, Jr. S. Sutton-Jones, and C. Medina. August 1997, 20–24.
- Calibration and Validation of UV-Vis Absorption Spectrophotometers. A.C. Richardson and J.D. Messman. August 1997, 7.
- Complete Automation of the Bacterial Endotoxin Assay. K.L. Williams. June 1997, 46–57.
- The Use of Model Solvents for Evaluating Extractables from Filters Used to Process Pharmaceutical Products, Part 2: Assigning a Model Solvent. C.J. Weitzmann. May 1997, 72–78.
- The Use of Model Solvents for Evaluating Extractables from Filters Used to Process Pharmaceutical Products, Part 1: Practical Considerations. C.J. Weitzmann. April 1997, 44–59.
- Test Method Development and Validation. C. DeWain and C.V. Sutton. April 1997, 60–63.
- In-Process Control for Large-Scale Animal Cell Culture. G. MacMichael. March 1997, 38–40.
- Avoiding Instrument-Associated Aberrations in Purification Scale-Up and Scale-Down. P. Gagnon. March 1997, 42–45.
- A Rapid Validation Approach: Reducing the Time and Costs Associated with Validation. S. Buchholz. January 1997, 50–53.
- A Holistic Approach to GLP and cGMP Compliance. J.R. Christensen. January 1997, 16–18.
- Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products: Highlights from the New PDA Technical Report No. 34. R.E. Madsen. July 2001, 30–32.

Water Systems

Industry Trends

- Glycobiology is Growing. J.C. Klock. July 1998, 31–33.
- Homologous Recombination in CHO Cells. M. Reff. July 1998, 33–34.
- High-Throughput Synthesis and DNA Chips. R.J. Molinari. July 1998, 34–36.
- Chaos, Speed, and Value Curves: Capitalizing on Emerging Trends. M. Caple. July 1998, 36–38.

Tutorials

Inside Washington Columns

- "Research and Regulations" in Inside Washington. J. Wechsler. March 2001, 48–52.
- "Fees and Funding for Biotechnology" in Inside Washington. . November 2000, 22–26.
- Research Practices and Industry Prices Under Attack. J. Wechsler. October 2000, 26–30.
- USP Tackles Standards for Biologics. J. Wechsler. September 2000, 30–35.
- Accelerating Biotech Development and Approval. J. Wechsler. July 2000, 24–28.
- "Is Team Biologics Working?" in Inside Washington. J. Wechsler. February 2001, 50.
- "Challenges for the Genomics Era" in Inside Washington. J. Wechsler. April 2001, 44–48.
- The Year Ahead - Reform and Regulatory Challenges. J. Wechsler. January 2001, 48–49.
- Emphasis on Enforcement. J. Wechsler. August 2000, 22–25.
- Expensive Pipeline Therapies Under Attack. J. Wechsler. June 2000, 20–24.
- Patents, Privacy, and Gene Research. J. Wechsler. May 2000, 20–24.
- Safety, Bioterrorism, Research: Top White House Priorities. J. Wechsler. April 2000, 20–23.
- Medication Errors Draw Congressional Scrutiny. J. Wechsler. March 2000, 22–26.
- "Biotechnology in the Limelight" in Inside Washington. J. Wechsler. January 2000,

20–24.

- Medicare, Prices, and Research. J. Wechsler. November 1999, 22–26.
- Changes at FDA and CBER Reflect New Priorities and Pressures. J. Wechsler. October 1999, 20–24.
- "Biologics, CTDs, and BSE" in Inside Washington. J. Wechsler. May 2001, 60–64.
- Stability at Home and Abroad. J. Wechsler. June 1999, 14–22.
- Safety, Quality, and Resources. J. Wechsler. May 1999, 10–16.
- "Risk and Regulation at FDA" in Inside Washington. J. Wechsler. June 2001, 64–67.
- FDAMA Reshapes FDA. J. Wechsler. April 1999, 12–16.
- New FDA Commissioner Faces Major Challenges. Jill Wechsler. January 1999, 15–18.
- "Politics and Policies" in Inside Washington. J. Wechsler. July 2001, 45–50.
- Coping with Compliance Changes. J. Wechsler. July 1998, 18–22.
- Marketing Issues Raise Concerns for Biotech Manufacturers. J. Wechsler. November 1998, 16–20.
- Harmonizing Biologics and Drugs. J. Wechsler. October 1998, 16–19.
- New Commission, New Challenges. J. Wechsler. September 1998, 12–20.
- Harmonization at Home and Abroad. J. Wechsler. May 1998, 24–26, 43.
- Rescuing the "R" in CBER. J. Wechsler. April 1998, 10–14.
- FDA Adopts Electronic Systems. J. Wechsler. March 1998, 12–16.
- FDA Faces "Modernization". J. Wechsler. January 1998, 10–13.
- Overhauling Inspections and Regulations of Biologics. J. Wechsler. November 1997, 14–18.
- New Market Potential for Biotech Drugs. J. Wechsler. October 1997, 20–22.
- "Reinventing and Harmonizing Biotech Regulation" in Inside Washington. J. Wechsler. September 1997, 16–18, 59.
- Regulatory Reform Boosts QC. J. Wechsler. August 1997, 5152.
- Threats to Biomedical Research and Privacy. J. Wechsler. June 1997, 20–24.
- "Medicare Reform and Drug Reimbursement" in Inside Washington. J. Wechsler. May 1997, 20–28.
- Congress Debates FDA Fees and Funding. J. Wechsler. April 1997, 12–16.
- Reinventing Inspections and GMPs. J. Wechsler. March 1997, 26–28, 37.
- New Initiatives, New Commissioner in 1997. J. Wechsler. January 1997, 22–26.

GMP Issues Columns

- GMP Issues: On Complying with 21 CFR 11. B.K. Immel. August 2000, 59–61.
- Step Up to the Responsibility of QA and QC. B. Immel. February 2000, 58–60.
- Improving Your Training Program. B.K. Immel. August 1999, 31–34.
- An Electronic Eye Opener. B. Immel. June

1999, 60–63.
 The Forgotten GLPs. B.K. Immel. April 1999, 40–43.
 New Beginnings. B.K. Immel. January 1999, 52–55.
 Reflections in the Mirror, Part 2: Working with Clients. B.K. Immel. November 1998, 51–53.
 Reflections in the Mirror, Part 1: Working with Contractors. B.K. Immel. October 1998, 44–47.
 The Write Approach: A Guest Editorial. . August 1998, 8.
 The Essence of Training, Part 2: “The Play’s the Thing”. B.K. Immel. June 1998, 62–67,70.
 The Essence of Training, Part 1. B.K. Immel. May 1998, 90–95,100.
 Environmental Monitoring and Other Facts of Life. B.K. Immel. March 1998, 46–49.
 Meeting Requirements of the European Union. B.K. Immel. January 1998, 46–49.
 Changing Times, Changing Ideas. B.K. Immel. November 1997, 62–63,66.
 30 Tips to Bring You Closer to Compliance. B.K. Immel. September 1997, 66–68,71.
 The Art of GMP Auditing. B.K. Immel. June 1997, 58–64.
 “Working Successfully with FDA” in GMP Issues. B.K. Immel. May 1997, 80–87,95.
 On Compliance Leadership. B.K. Immel. April 1997, 69–70.
 Preparing for a Major Inspection. B.K. Immel. March 1997, 49–51.
 Excellent Training Begins with Training That Counts. B.K. Immel. January 1997, 24–28.
 Working with FDA. B.K. Immel. January 1997, 32–36.
 “Documentation Revisited” in GMP Issues. B.K. Immel. January 1997, 8–12.
 “Passionate About Change Control” in GMP Issues. B.K. Immel. January 1997, 14–15,22.
 “How You Can Use Everything You Make” in GMP Issues. B.K. Immel. January 1997, 20–22.
 “Marketing 101 for Trainers and Other Smart People” in GMP Issues. B.K. Immel. January 1997, 29–31.
 “Working with Teams” in GMP Issues. B.K. Immel. January 1997, 37–39.

Outsourcing Outlook Columns

Applying the Theory of Constraints. J. Miller and L. Michalski. September 2000, 24–28.
 “Aligning Client and Contractor Objectives” in Outsourcing Outlook. J. Miller and J. Michalski. March 2001, 58–62.
 “Audits Aren’t Enough to Ensure Quality” in Outsourcing Outlook. J. Miller and L. Michalski. April 2001, 54–58.
 Balancing the Benefits of Outsourcing. J. Miller L. Michalski, and K.K. Glass. January 2001, 52–56.
 “Technical Innovations in Data Management” in Outsourcing Outlook. J. Miller and L. Michalski. November 2000, 16–20.
 Succession Planning. J. Miller and L. Michalski.

August 2000, 16–20.
 Don’t Overlook Cultural Differences. J. Miller and L. Michalski. July 2000, 14–18.
 How to Identify Vendor Risk. J. Miller and L. Michalski. October 2000, 20–25.
 Contract Laboratory Services 2000 Survey. J. Miller M. Levin-Epstein, and L. Michalski. June 2000, 14–18.
 Effective Communication Equals Successful Project Management. J. Miller and L. Michalski. May 2000, 14–18.
 Chief Resource Officers. J. Miller and L. Michalski. April 2000, 16–19.
 Benchmarking for the Bottom Line. J. Miller and L. Michalski. March 2000, 17–20.
 Toward More Strategic Outsourcing. J. Miller and L. Michalski. February 2000, 17–20.
 “Minimizing Loss in a Risky Business” in Outsourcing Outlook. J. Miller and L. Michalski. January 2000, 10–18.
 Restructuring of Big Pharma Could Lead to Big Opportunities for Contract Manufacturers. J. Miller. November 1999, 16–20.
 “Technology Lessons from the E-Marketplace Shakeout” in Outsourcing Outlook. J. Miller. May 2001, 70–74.
 “Managing the Risks in Outsourcing” in Outsourcing Outlook. J. Miller. June 2001, 70–72.
 “Performing Due Diligence on Private CROs” in Outsourcing Outlook. J. Miller and L. Michalski. July 2001, 56–58,70.

Info+

Patent Law You Can Use Columns

“Provisional Patent Applications” in Patent Law You Can Use. H.M. Eisenberg. March 2001, 66–68.
 “Rule 56 — Duty of Candor and Good Faith” in Patent Law You Can Use. . November 2000, 64–65.
 Patentability Searching. H.M. Eisenberg. October 2000, 74–76.
 Maintaining Laboratory Notebooks. H.M. Eisenberg. September 2000, 68–69.
 Inventorship vs. Ownership. H.M. Eisenberg. July 2000, 68–70.
 Continuation Patent Applications Use. H.M. Eisenberg. January 2001, 59–61.
 Recent Changes in U.S. Patent Law. H.M. Eisenberg. May 2000, 60–61.
 Inventorship. H.M. Eisenberg. March 2000, 56–57.
 Patent Filing Deadlines and Bars to Patentability. H.M. Eisenberg. February 2000, 56–57.
 Reading a Patent: Part 2, The Description and the Claims. H.M. Eisenberg. November 1999, 61–62,64.
 “Foreign Patent Applications” in Patent Law You Can Use. H.M. Eisenberg. May 2001, 76–77.
 “Reading a Patent: Part 1, the Cover Page” in Patent Law You Can Use. H.M. Eisenberg. September 1999, 14–18.
 Types of Intellectual Property, Part 1. H.M. Eisenberg. April 1999, 38–39,43.

“Foreign Patent Applications: The Patent Cooperation Treaty” in Patent Law You Can Use. H.M. Eisenberg. July 2001, 59–60.

Your Vested Interest Columns

“Other People’s Money” in Your Vested Interests. . November 2000, 62–63.
 Viewpoint: The New Science of Investing. B.H. Rudolph and V. Aslam. September 2000, 20–22.
 “Science in the Mannerist Style” in Your Vested Interests. B.H. Rudolph and V. Aslam. February 2001, 68–70.
 “The Joys of Voodoo” in Your Vested Interests. B.H. Rudolph and V. Aslam. April 2001, 59–60.
 Buy! Sell! Hold!. B.H. Rudolph and V. Aslam. January 2001, 62–64.
 Your Vested Interests:: Image Is Everything. B.H. Rudolph and V. Aslam. October 2000, 68–72.
 “Is the Sky Really Falling?: Looks like it — and it’s all my fault” in Your Vested Interests. B.H. Rudolph and V. Aslam. May 2001, 78–79.
 “Sector Spotlight: Molecular Evolution Companies” in Your Vested Interests. B.H. Rudolph and V. Aslam. June 2001, 73–75.