Thomas N. Feinberg, Ph.D.
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SUMMARY

Results-oriented Research and Development Executive with particular emphasis on Analytical Development and recognized expertise in Extractables and Leachables

CAPABILITIES

- CMC Documentation Review
- Analytical Development Program Management
- Analytical Method Remediation / Gap Analyses
- Extractables and Leachables Project Design / Project Management
- OOS Investigation Documentation / Root Cause Analyses
- Form 483 Response Preparation / Project Management
- Pharmaceutical Technology Assessments
- Technical Data Audit Support / Data Integrity Evaluations
- Contract Analytical Service Vendor Management / RFP Development
- Standard Operating Procedures / 21CFR 211 Compliance
- Computer System Validation / 21CFR Part 11 Compliance
- Breakthrough Lean Program Development
- Lean Sigma Project Sponsorship
- Laboratory and Quality Process Mapping
- Technical Staff Training Module Development / Deployment
- Technical Staff Organizational Design / Implementation

PROFESSIONAL EXPERIENCE

2014-present

President
SCIO Analytical, LLC

Provides expert consultation services to pharmaceutical manufacturers and prospective vendors into this regulated industry. Specialty in Extractables and Leachables testing program design/remediation, CMC documentation review, Data Integrity Audits and strategies for compliance with future world-wide regulatory initiatives.

2012-2014

Senior Director – Scientific Affairs
Development and Analytical Solutions
Catalent Pharma Solutions, LLC

Conducted primary market research for contract analytical services, vendor alliances and strategic acquisitions. PM for successful validation and installation of proof-of-concept global LIMS (SQL*LIMS P4) and site's first MHRA audit response. Designed and presented directly at FDA the analytical platform strategy for the Advasept® sterile packaging format.

2006-2012

Director – Structural Chemistry
Development and Clinical Services
Catalent Pharma Solutions, LLC

Directed Laboratory, Metrology, EH&S, and OpEx groups consisting of 50 technical staff. Sponsored first successful OpEx projects for facility including Breakthrough LEAN deployment to over 200 employees which doubled OTD and FPA in 6 months. PM for closure of San Diego facility which minimized cost and regulatory risk (including environmental assessments) to Catalent and clients.

2004-2006 Director – Analytical Services
Respiratory, Analytical and Biotechnology Services
Cardinal Health, Pharmaceuticals and Technology Services

Site leader for all non-pulmonary CMC services including QC, stability, and stability storage. Developed and deployed career ladder and performance management process to 120 technical employees. Implemented metrics focus to improve report quality (First Pass Acceptance, FPA) and on-time delivery (OTD). PM for closure of Stockport, UK facility and transfer of all methods and materials to US sites.

2001-2004 Associate Director - Structural Chemistry
Cardinal Health, Pharmaceuticals and Technology Services

Organized and hired team leaders for mass spectrometry, trace inorganic analysis (atomic spectroscopy), NMR, and degradation chemistry. Designed protocols for stability analysis per ICH and FDA requirements. Active member of PQRI Extractables and Leachables in Orally Inhaled and Nasal Drug Products (OINDP) WG. Doubled both revenue and operating income in 3 years.

1999-2001 Section Head - Mass Spectrometry and Trace Organic Analysis
Magellan Laboratories, Inc.

Developed container-closure extractables and leachables control strategies for MDIs, DPIs, Inhalation Solutions, Parenterals, Injectables and Topicals. Study Director for over 50 GLP/GMP and ICH-compliant method development, method validation and investigational projects. Established and managed both efficiency metrics and cost-containment strategies to turnaround profitability.

1995-1999 Scientist I - Scientist II – Mass Spectrometry
Magellan Laboratories, Inc.

Conducted LC/MS and GC/MS studies for structural elucidation of drug product and drug substance impurities/degradants in a GLP/cGMP environment. Wrote SOPs and instrument calibration procedures per cGMPs. Developed bioanalytical methods for in vitro and in vivo screening for discovery support. Wrote over 30 submission-quality reports.

1991-1995 Postdoctoral Research Assistant / Associate
Departments of Chemistry and Environmental Sciences and Engineering
University of North Carolina at Chapel Hill

Developed derivatization methodology for trace detection of multi-functional carbonyls using CZE/UV/ESI mass spectrometry and ion trap GC/MS. Designed new laser-based experiment to obtain accurate ionization potentials of molecules and compared results to *ab initio* quantum mechanical calculations.

EDUCATION

1991 Ph.D. in Physical Chemistry
Dissertation: "Infrared and Mass Analyzed Ion Kinetic Energy Spectroscopy of Cluster Ions"
University of North Carolina at Chapel Hill, Chapel Hill, NC

1985 A.B. in Chemistry
Cornell University, Ithaca, NY

AFFILIATIONS PQRI, IPAC-RS, PDA, AAPS, ACS, ASMS, USP Expert Committee

SELECTED PUBLICATIONS

Feinberg, T. "Extractables and Leachables: Best Practices to Ensure Patient Safety," Pharmaceutical Technology, July 2013

Jenke, D.; Castner, J.; Egert, T.; Feinberg, T.; Hendricker, A.; Houston, C.; Hunt, D.G.; Lynch, M.; Shaw, A.; Nicholas, K.; Norwood, D.L.; Paskiet, D.; Ruberto, M.; Smith, E.J.; Holcomb, F. "Extractables Characterization for Five Materials of Construction Representative of Packaging Systems Used for Parenteral and Ophthalmic Drug Products," PDA Journal of Pharmaceutical Science and Technology 2013, Volume 67

Feinberg, T. "Critical Design Strategies for Extractables and Leachables Control: Methods for Avoiding Contamination," Contract Pharma, April 2013

Feinberg, T.N.; Norwood, D.N.; Granger, A.T.; Jenke, D. "Extractables – The Controlled Extraction Study" in Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products (D.J. Ball, D.L. Norwood, C.L.M. Stults, and L.M. Nagao, Eds), Chapter 14, January 2012

Norwood, D.N.; Feinberg, T.N.; Mullis, J.O.; Pennino, S. "Analytical Techniques for Identification of Extractables and Leachables" in Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products (D.J. Ball, D.L. Norwood, C.L.M. Stults, and L.M. Nagao, Eds), Chapter 13, January 2012

Norwood, D.N.; Mullis, J.O.; Feinberg, T.N.; Davis, L.K. "N-Nitrosamines as "Special Case" Leachables in a Metered Dose Inhaler Drug Product," PDA Journal of Pharmaceutical Science and Technology 2009, Volume 63

Norwood, D.L.; Paskiet, D.; Ruberto, M.; Feinberg, T.; Schroeder, A.; Poochikian, G.; Wang, Q.; Deng, T.J.; DeGrazio, F.; Munos, M.K.; Nagao, L.M. "Best Practices for Extractables and Leachables in Orally Inhaled and Nasal Drug Products: An Overview of the PQRI Recommendations," Pharmaceutical Research 2008, Volume 25

WORKSHOPS

"Extractables and Leachables Studies for Biological and Other 'High Risk' Dosage Forms," delivered at the Eastern Analytical Symposium, Somerset, NJ, November 2012

"Best Practices for OINDP Pharmaceutical Development Programs Leachables and Extractables," delivered at the Product Quality Training Course Program, San Diego, CA, November 2007

"Best Practices for OINDP Pharmaceutical Development Programs Leachables and Extractables," delivered at the Product Quality Training Course Program, Basel, Switzerland, September 2007

"Best Practices for OINDP Pharmaceutical Development Programs Leachables and Extractables," delivered at the Product Quality Training Course Program, Chicago, IL, April 2007

SELECTED PRESENTATIONS

Feinberg, T.N. "Bridging the Divide: Use of Simulation Studies to Resolve the Parenteral and Ophthalmic Drug Products (PODP) Analytical Challenge," presented at the USP/PQRI Joint Workshop on Suitability and Compatibility for Packaging and Delivery Systems Workshop Co-Sponsored by USP and PQRI, Rockville, MD, April 27-28, 2014

Feinberg, T.N. "What's good for OINDP (Orally Inhaled and Nasal Drug Products) may not be good for PODP," presented at the E&L USA Conference, Rockville, MD, May 16, 2012

SELECTED PRESENTATIONS (continued)

Feinberg, T.N. "Characterization of Trace Impurities Leaching from Pharmaceutical Packaging Systems" presented at 2011 Conference on Small Molecule Science, Chapel Hill, North Carolina, August 2-4 2011

Feinberg, T.N. "The Parenteral Ophthalmic Drug Product Leachables and Extractables Working Group: Status and Outlook" presented at International Pharmaceutical Aerosol Consortium-Regulatory Science 2011 Conference, Washington, D.C., March 29-31 2011

Feinberg, T.N. "Challenges and Best Practices in Extractable and Leachables" presented at 2009 Professional Dinner Meeting Series Parenteral Drug Association (PDA) West Coast Chapter, San Francisco, California, January 19 2009

SELECTED POSTERS

Feinberg, T.N.; Hendricker, A.D.; Cvetich, P.; Tonkiha, N.; Covington, L.; Cree, M.; Lennon, III, J.D.; Carico, L.; Jenke, D.; Maniak, P.; Egert, T. "Controlled Extraction and Simulation Study Results," presented at the USP/PQRI Joint Workshop on Suitability and Compatibility for Packaging and Delivery Systems Workshop Co-Sponsored by USP and PQRI, Rockville, MD, April 27-28, 2014

Hendricker, A.D.; Feinberg, T.N.; Tonkiha, N.; Covington, L.; Cree, M.; Cvetich, P.; Carico, L.; Lennon, III, J.D.; Castner, J.; Maniak, P.; Jenke, D. "Migration Study Test Results," presented at the USP/PQRI Joint Workshop on Suitability and Compatibility for Packaging and Delivery Systems Workshop Co-Sponsored by USP and PQRI, Rockville, MD, April 27-28, 2014

Carroll, C.A.; Kolbert, A.C.; Feinberg, T.N. "Detection of Residual Solvents in a Large-Molecule API by 1H NMR Spectroscopy" presented at 2009 American Association of Pharmaceutical Scientists Meeting and Exposition, Los Angeles, California, November 7-12 2009

Carroll, C.A.; DeRider, M.D.; Feinberg, T.N. "Detection of Adulterants in Raw Materials, Drug Substances, and Products by NMR Spectroscopy" presented at 2009 American Association of Pharmaceutical Scientists Meeting and Exposition, Los Angeles, California, November 7-12 2009

Carroll, C.A.; Kolbert, A.C.; Feinberg, T.N. "Determination of API:Counter Ion Ratio in Soft-Gelatin Capsules by Quantitative 13C Nuclear Magnetic Resonance (NMR) Spectroscopy" presented at 2008 American Association of Pharmaceutical Scientists Meeting and Exposition, Atlanta, Georgia, November 16-20 2008

Hendricker, A.D.; Deal, A.L.; Feinberg, T.N. "Case Study: Method Optimization and Extractables Characterization of Peroxide Cured Rubber" presented at the PQRI Leachables & Extractables Workshop, Bethesda, MD, December 5-6 2005