EDWARD K. CHESS

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EXECUTIVE SUMMARY

Senior Analytical Research Chemist with expertise solving problems for the pharmaceutical industry. Skilled at structure elucidation and using chromatography and mass spectrometry to develop and test product, container/closure systems, and devices.

Technical Management
- Department manager for physical and chemical sciences groups conducting R&D (up to 80 scientists).
- Budget management (up to $8M OPEX).
- Oversight of personnel conducting cGMP and cGLP studies.

Laboratory Management
- Strategic responsibility for building, staffing, and maintaining state of the art laboratories for structure elucidation, microscopy, and imaging.
- Familiar with FDA, ICH, and USP guidelines for laboratory operations.

Research and Development/Manufacturing Support
- Material characterization and selection for container closure systems for medical devices and intravenous fluids.
- Expertise in material compatibility (including extractables and leachables assessments).
- 26 years of problem solving for a wide array of manufacturing issues for pharmaceutical products.

Analytical Chemistry
- Expertise in chemical structure determination using mass spectrometry and chromatography.
- Working knowledge of NMR, IR, UV-Vis spectroscopies.
- Experience in analytical method development, evaluation, and validation.
- Member USP Expert Panels for unfractionated and low molecular weight heparins (co-chair).

PROFESSIONAL EXPERIENCE

BAXTER HEALTHCARE, Round Lake, IL **1988 to 2014**

Baxter products provide critical, life-saving, and life-sustaining therapies for patients with hemophilia, end-stage renal disease, primary immune deficiency, and diseases requiring intravenous medications in hospital and home care settings.

Senior Director, Research (2003 - 2014)

Promoted to lead a physical and chemical sciences department of professionals focused on providing core analytical capabilities for Baxter divisions worldwide. Challenged to improve capabilities to support new product development and existing product maintenance, including global manufacturing troubleshooting. Responsible for up to $8M budget.

- Provided technical and executive management of Physical and Chemical Sciences Department, a group of up to 70 scientists focused in the area of analytical chemistry, analytical biochemistry, particle science and morphology, and synthetic chemistry. Oversaw groups designing, developing, and implementing services to support research, development, and manufacturing activities, including GLP- and cGMP-compliant laboratory experiments.

- Key contributor to FDA approval of IV solutions container closure system comparability protocol. Compressed approval of material change control from 18 months to 1 month. Earned 2006 Baxter Medication Delivery Outstanding Contribution Award: Comparability Protocol Approved for Improved Packaging Change Control.
- Technical team lead for heparin contamination investigation, following product complaints from the field. Isolated lots and recalled product to identify root cause, and determined the structure of the contaminant in the crude heparin from China. Resolved the contaminant structure within eight weeks, and developed methods to test for the contaminant in heparin products. FDA adopted the testing methods as the emergency response. 2007 Baxter Corporate Customer First Award. Solving the Heparin Mystery – Leading the Way.
- Worked with a US manufacturer of heparin to establish a product that would meet the new USP Heparin Sodium monograph criteria, and relaunch the product in the US. Earned 2008 Baxter Technology Resources Alliance Award. Heparin Relaunch.
- Work with the USP and FDA led to invitation to join the USP Heparin Advisory Panel, which received the 2010 United States Pharmacopeia Award for an Innovative Response to a Public Health Challenge.

Senior Technical Director (1998 - 2003)
Promoted to provide technical management of group of 45 analytical, and synthetic organic chemists (Team Leader, Chemistry); responsible for $4MM budget. Managed design, development and implementation of analytical chemistry analyses and other chemistry services to support research, development, and manufacturing activities. Conducted and directed GLP- and cGMP-compliant laboratory experiments.

- Participated in award winning container development efforts, resulting in the launch of products in new container systems, including non-DEHP IntraVia Pre-Mix Container system. Received multiple awards including the 1998 Baxter Center for Physical and Chemical Sciences Award: Extractives Assessment, IntraVia Prmix Container, and the 1999 Baxter Center for Physical and Chemical Sciences Award: Extractives Evaluation of 50-mL PL 2408-3 Containers for DMF Update.

Technical Director (1995 - 1998)

Senior Research Scientist (1988 - 1995)

BATTELLE PACIFIC NORTHWEST LABORATORY, Richland, WA **1981 to 1988**
National laboratory conducting Department of Energy research in nuclear reactor design and waste storage.

Research Scientist (1981 - 1988)
Applied research and development; qualitative and quantitative analysis of complex mixtures, including coal-derived fuels, fly-ash, and DNA-adducts, by combined chromatographic/mass spectrometric techniques; instrument development; program management.

EDUCATION

Ph.D., University of Nebraska, Lincoln, NE, May 1982

B.S., The College of Idaho, Caldwell, ID, May 1976

RECENT PUBLICATIONS

Tummala, M., P. Hu, S.-M. Lee, A. Robinson, E. Chess. 2008. Characterization of pertussis toxin by LC-MS/MS. Anal. Biochem. 374: 16-24.

Hu, P., L. Fang, and E. K. Chess. 2009. Source-induced fragmentation of heparin, heparan, and galactosaminoglycans and application. Anal. Chem. 81(6): 2332-2343.

Tummala, M., S.-M. Lee, E. Chess, P. Hu. 2010. Characterization of pertussis toxoid by two-dimensional liquid chromatography-tandem mass spectrometry. Anal. Biochem. 401: 295-302.

McKee J, S. Bairstow, C. Szabo et al. 2010. Structure elucidation and biological activity of the oversulfated chondroitin sulfate contaminant in Baxter heparin. J Clin Pharmacol. 50(10):1159-70

Lee, S. F., E. K. Chess, B. Rabinow et al. 2011. NMR of heparin API: Investigation of unidentified signals in the USP-specified range of 2.12 – 3.00 ppm. Anal. Bioanaly. Chem. 399: 651-662.

Hu, P., L Fang, C.M. Jones, E., K. Chess. 2011. Collective sampling of intact polysaccharide components and application in quantitative determination by LC-MS. Carb. Res.346: 2268-2273.

Zhang, Z., N. M, Khan, K M. Nunez, E. K. Chess, C. M. Szabo. 2012. Complete Monosaccharide Analysis by High-Performance Anion-Exchange Chromatography with Pulsed Amperometric Detection. Anal. Chem. 84: 4104-4110.

Chess, E. K., S. Bairstow, S. Donovan, K. Havel, P. Hu, et al. 2012. Case study: contamination of heparin with oversulfated chondroitin sulfate. In Handb Exp Pharmacol. 207:99-125.

Tummala, M., A. Chacon, E. K. Chess, S.-M. Lee, P. Hu. 2013. Pertussis toxoid structure: A collaboration and comparison of two-dimensional liquid chromatography-tandem mass spectrometry, ultraperformance liquid chromatography-mass spectrometry^{E}, and capillary liquid chromatography-matrix -assisted laser desorption ionization-tandem mass spectrometry. Anal. Biochem. 437(1):40-42.