



Pedro E. Hernández Abad, Ph.D.

SUMMARY

Well known thought leader in Quality by Design (QbD) and Process Analytical Technology (PAT) with practical, real world experience in the implementation of these important tools to reduce risk and improve efficiency in pharmaceutical manufacturing. Dr. Hernandez's experience in relations with regulatory bodies, drug substance and drug product manufacture, problem-solving, process chemistry, and medicinal chemistry gives him a unique perspective and valuable set of skills for Rondaxe clients.

KEY SKILLS

API synthesis, characterization, scale-up and cGMP supply, Method Validation, Formulation, Drug Substance and Drug Product Technology Transfer; Project, Personnel and Budget Management, Asset Utilization, QbD, CRO/CMO B2B Experience, PAT Instrument Selection/Design/Construction, Automation, Spectroscopy, Risk Management, Risk Mitigation using PAT Tools, Design of Experiments, Method Development, International Multicultural Experience, CMC, BOH (FDA, EMEA, IMB) and ICH.

PROFESSIONAL EXPERIENCE

Pedro Hernandez Process Development (PHPD) 2010 – Present

Quality by Design/Process Analytical Technology Consultant from Drug Substance to Drug Product

- Consultant on QbD, PAT, Quality Risk Management and Life Cycle Management, in the US and ROW.
- Industry experience from API synthesis to finished drug product manufacturing using a variety of technology platforms in the USA and internationally.
- Advise on regulatory strategy, PAI, POV, QbD, PAT, CMC and experience with Boards of Health (FDA, EMEA, IMB) and ICH.

Pfizer, Inc., Pearl River, NY 2009 – 2010

Associate Director QbD/PAT, Pharmaceutical Development Center, Pearl River, NY

Wyeth Pharmaceuticals Co., Guayama, Puerto Rico (PR) and Pearl River, NY 2004 – 2009

Associate Director QbD/PAT, Pharmaceutical Development Center, Pearl River, NY (2008 – 2009)

- Feasibility, development and implementation of PAT for pipeline and commercial products
- Develop and implemented PAT tools for commercial manufacturing for internal and external customers in Ireland, Switzerland, Germany, Canada and Puerto Rico leading to process robustness and value added
- Lead Wyeth global network of PAT scientists to harmonize practices and share knowledge
- Member of the Drug Substance/Drug Product Specification Committee

Principal PAT Scientist II (2007 – 2008, Puerto Rico and NY)

- Responsible for Active Pharmaceutical Ingredients (API) and Process Analytical Technology (PAT) implementation, PR and NY
- Developed and Implemented PAT in the commercial manufacturing of Pristiq® as part of the FDA QbD Pilot Program
- Developed Training, Risk Assessments, Analytical Methods, SOPs and Quality Systems towards cGMP PAT implementation for commercial manufacturing
- Participated in Boards of Health (FDA, EMEA, IMB) Pre-Approval Inspections and audits. Pristiq® obtained Real Time Release testing approval by the FDA



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Senior Scientist II, Technology Transfer to cGMP manufacture, PR (2004 – 2006, Puerto Rico)

- Technology Transfer Lead for Registration, Validation and commercial launch of Lybrel® and Pristiq®
- Technology Lead for scale-up from R&D to commercial manufacturing

Albany Molecular Research, Inc., Albany, NY

1996 – 2003

Senior Research Chemist II, Medicinal Chemistry and Chemical Development

- Responsible for process development of syntheses destined for GMP manufacture and laboratory manager responsible for customer relations and management of several projects and 8 to 12 chemists
- Technology transfer of projects to Organichem and external manufacturers (US and International), Route discovery and optimization of existing processes, Kilo lab non-GMP and GMP manufacture
- Pre-clinical and clinical API supply for multiple projects/customers (US and International)
- Bid preparation, budget and resources management, customer relations as the primary B2B contact, API specifications determination, methods development and transfer
- Design and synthesis of new drug candidates. QSAR

Zynaxis, Inc., Malvern, PA

1995 – 1996

Investigator

- Design and synthesis of heparin bio-conjugates with therapeutic application in restenosis using stents
- Synthesized lead compound and developed new HPLC and NMR methods for the characterization of novel type compounds with smooth muscle cell antiproliferative activity

Johnson Matthey Biomedical Research, West Chester, PA

1992 – 1995

Senior Research Chemist

- Design and synthesis of new imaging agents, bioconjugates, chemotactic peptides, peptidomimetics, antiviral macrocycles (HIV) and anticancer agents
- Authored three patents, two publications and synthesized the 2nd generation lead compound

SmithKline Beecham, King of Prussia, PA

1992

Visiting Scientist

- Michael Induced Ring Closures (MIRC) towards chiral cyclopropanes.

Cayey University College, Department of Chemistry -U.P.R., Cayey, Puerto Rico

1991 – 1992

Assistant Professor (Organic)

- General and Organic chemistry lecture and laboratory instruction
- Coordinator of academic-industry work study program

USDA - Agricultural Research Service, Gainesville, FL

1988 – 1991

Research Associate

- Synthesis of insect pheromones
- Structure activity relationship studies of insect pheromones

EDUCATION

- **Postdoctoral**, University of Oxford, Oxford, United Kingdom, 1986 – 1988
 - Advisor: Prof. George W.J. Fleet, carbohydrate chemistry
- **PhD, Chemistry**, University of Pennsylvania, Philadelphia, PA, 1981 – 1986



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- Advisor: Prof. K.C. Nicolaou, natural products synthesis
 - **BSc, Chemistry**, University of Puerto Rico, San Juan, Puerto Rico, 1977 – 1981
 - Advisor: Prof. Waldemar Adam, photochemistry

AWARDS

- Best Practice Award – 2009: Process Analytical Technology, Wyeth Pharmaceuticals, NY, 2009
- SmithKline Beecham Visiting Scientist Fellowship, King of Prussia, Pennsylvania, 1992
- Faculty Research Grant CUC-MBRS Advisory Committee
Cayey University College-UPR, Cayey, Puerto Rico, 1991
- Science and Engineering Research Council Research Fellowship
Dyson Perrins Laboratory, University of Oxford, United Kingdom
- National Science Foundation Graduate Minority Fellowship
University of Pennsylvania, Philadelphia, Pennsylvania

PATENTS

US Patents:

- 4,759,880; 5,350,837; 5,792,444; 5,817,807, 6,239,277, 6,265,579

International Patents:

- EP 569132, EP 747368, WO 9511045, WO 0129016, WO 0132641

PUBLICATIONS & PRESENTATIONS

1. J. Huang et.al. A PAT Approach to Improve Process Understanding of High Shear Wet Granulation Through In-line Particle Measurement using FBRM C35. *J. of Pharm. Sciences*. 2010, 99: 3205–3212.
2. Hernandez, Pedro: “QbD/PAT: From Science to Compliance Part I: Background and Challenges”, and “QbD/PAT: From Science to Compliance Part II: Implementation and Sustainability”, International Pharmaceutical Academy, Somerset NJ, October 19-20, 2009
3. Hernandez, Pedro: “QbD/PAT: From Science to Compliance”, AMRI Chem. Dev. Symposium, Albany NY, August 26-27, 2009
4. J. Huang, G. Kaul, C. Cai, R. Chatlapalli, P. Hernandez-Abad, K. Ghosh, A. Nagi. Quality by design case study: An integrated multivariate approach to drug product and process development. *International Journal of Pharmaceutics*, 382 (2009) 23-32
5. P. Hernandez, J. Huang, S. Romero-Torres. QbD and PAT: From Science to Compliance. *European Pharm Review*. Issue 4, 2009
6. J. Huang et.al. A PAT Approach to Enhance Process Understanding of Fluid Bed Granulation using In-line Particle Size Characterization and Multivariate Analysis. Submitted to *J. of Pharmaceutical Innovation*. (2010) 5:58–68
7. S. Romero-Torres, J. Huang, P. Hernandez. Practical considerations in PAT analyzer selection: NIR vs.Raman. *American Pharmaceutical Review*. Nov/Dec 2009
8. Hernandez, Pedro, Carroll, J.E.: “The Role of PAT and QbD in Biologic Drug Production: The Role of PAT in a Real Time Product Release Project”, Interphex PR, San Juan PR, February 14-15, 2008
9. Hernandez, Pedro: “API Process Discovery and DP QbD/PAT Implementation in Pharmaceutical Manufacturing”, Univ. of Pennsylvania, Department of Chemistry Seminar Series, Philadelphia PA, October 24, 2007

Pedro E. Hernández Abad, Ph.D.

10. Hernandez, Pedro: "Quality by Design - Process Analytical Technology, Wyeth's Implementation Strategy" PAT Implementation Strategies for Pharmaceuticals, International Quality & Productivity Center (IQPC), Philadelphia, PA April 11- 13, 2007
11. Hernandez, Pedro: "Quality by Design - Process Analytical Technology, Wyeth's Implementation Strategy", IFPAC-PAT Summit Presentation, June 14-15, 2007
12. Hernández, P.; Romero-Torres, S.; Radspinner, D.; Rodríguez-Hornedo, N.; Dougherty, J.J.; Romañach, R.J. "The Real Challenge is Moving to a PAT System – IFPAC/INDUNIV PAT Summit" J. of PAT, 2006, Nov-Dec 2006
13. Hernandez, Pedro: "Quality by Design (QbD) – PAT: An Approach to Real Time Release" IFPAC-PAT Summit Presentation, September 6-7, 2006
14. Hatse, S.; Princen, K.; De Clercq, E.; Rosenkilde, M.M.; Schwartz, T.W.; Hernández-Abad, P.E.; Skerlj, R.T.; Dominique Schols, D. "AMD3465, a monomacrocyclic CXCR4 antagonist and potent HIV entry inhibitor" Biochem. Pharmacol. 2005, 70, 752–761
15. Herr, R.J.; Zhichkin, P.; Hernández-Abad, P. E.; Meckler, H.; Schow. S.R. "An Efficient Synthesis of 2-Hydroxyethyl N,N,N',N'-Tetrakis(2-chloroethyl) phosphorodiamidate," Org. Proc. Res. Dev. 2001, 5, 442-444
16. Higgins, III, J.D.; Bridger, G.J.; Derian, C.K.; Beblavy, M.J.; Hernández, P.E.; Gaul, F.G.; Abrams, M.J.; Pike, M.C.; Solomon, H.F. "N-Terminus Urea-Substituted Chemotactic Peptides: New Potent Agonist and Antagonist toward the Neutrophil fFMF Receptor," J. Med. Chem, 1996, 39, 1013-1015
17. Nicolaou, K.C.; Chung, Y.S.; Hernández, P.E.; Taffer, I.M.; Zipkin, R.E. "Total Synthesis of 20-Hydroxy- and 20-Carboxy Leukotrienes B₄," Tetrahedron Letters, 1986, 27, 1881
18. Nicolaou, K.C.; Hernández, P.E.; Li, W.S.; Ladduwahetty, T.; Randall, J.L.; Webber, S.E.; Petasis, N.A. "Ethanoarachidonic Acids: A New Class of Arachidonic Acid Cascade Modulators. 2. Polyethano Compounds," J. Org. Chem, 1983, 48, 5403
19. Nicolaou, K.C.; Petasis, N.A.; Li, W.S.; Ladduwahetty, T.; Randall, J.L.; Webber, S.E.; Hernández, P.E. "Ethanoarachidonic Acids: A New Class of Arachidonic Acid Cascade Modulators. 1. Monoethano Compounds," J. Org. Chem, 1983, 48, 5400

COURSES

- Multivariate Data Analysis, Level 1, CAMO Software, Woodbridge NJ, October 14-15, 2009
- Communities of Practice, Wyeth, Andover, MA, January 16-17, 2008
- PAT: Enhancing Pharmaceutical production, in-process analysis, product quality and business operations The Center for Professional Advancement, New Brunswick, NK, June 6-8, 2006
- Project Management Fundamentals, CQPR, Rio Grande, PR, August 17, 2006
- Kepner-Tregoe Problem Solving and Decision Making, Wyeth, Guayama, PR, December 16, 2005
- Pharmaceutical Technology Summer School, Mixing Consultants, San Juan PR, May 23-27, 2005
- Statistics for non-statistic Managers, Wyeth, Guayama, PR, April 8, 2005
- Drug Development Training Session I: Wyeth, Collegeville, PA, September, 22-24, 2004
- Drug Development Training Session II: Wyeth, Collegeville, PA, November, 16-17, 2004
- Global Chemistry, Manufacturing and Control Challenges: From Drug Substance to Finished Product; Philadelphia, PA, Scientific Update, February 4-6, 2002
- Fundamentals of Chemical Processing for Bulk Drugs and Intermediates: Bridging the Gap between Chemistry and Engineering; Boston, MA, Scientific Update, May 16-18, 2001
- HPLC Troubleshooting; Albany Molecular Research, Inc., Albany, NY, April 25-26, 2001