

BINGIDIMI I. MOBELE, Ph.D.

SUMMARY

Expert process chemist with over 12 years of practical experience in the development of efficient, cost effective, and safe processes for the manufacture of multiple active pharmaceutical ingredients (APIs) and intermediates in a fast-paced environment. Additional expertise in solid state chemistry includes the screening and selection of developable solid forms for APIs, and the development and optimization of practical crystallization processes for salts, co-crystals and polymorphs of APIs and intermediates suitable for large scale production. Knowledgeable in the integration of biocatalytic processes into chemo-enzymatic syntheses, with hands-on experience in the use of yeasts for chiral reduction and an isolated oxidative enzyme in a coupled redox system for stereoselective oxidation of prochiral substrates. Founded a contract research laboratory and R&D outsourcing management and consulting firm offering custom synthesis, process R&D and manufacturing services to emerging Pharma and Biotech clients through a small network of CROs and CMOs in the US, Europe and Asia.

SKILLS

- Process R&D/Organic synthesis methodologies
- Design of Experiments (DoE)
- Crystallization process development
- API physical form screening, characterization, selection and optimization
- Biocatalysis/Chemo-enzymatic synthesis
- Bacterial and yeast cell culture, enzyme isolation and purification to homogeneity
- Written and verbal communication
- Creative problem solving
- Ability to bridge functional silos and effectively collaborate with cross-functional teams

PROFESSIONAL EXPERIENCE

OKAPI Chemtech, Inc., Rochester, NY

2010 - present

Founder and President

- Chemistry contract R&D, rapid response custom synthesis (up to 1-2 kg batches)
- Solid state screening services (salt, co-crystals, and polymorphs); crystallization process development and optimization
- Consulting on Chemical Development of APIs and Intermediates: assessment of synthetic routes to new drug candidates, process research, development, optimization and scale-up
- Assist clients with selection and execution of phase appropriate strategies and plans for research and development, as well as manufacturing of drug candidates, minimizing bottlenecks in drug substance procurement

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- Chemistry services vendor selection and management
- Management of outsourced chemistry projects at third parties offshore
- Consulting on solid state chemistry, including screening and selection of salts, co-crystals and polymorphs
- Consulting on the development of robust, scalable crystallization processes, including crystallization of complex polymorphic systems
- Technical writing (drafting, review and editing of chemical development reports, CMC section of regulatory filing dossiers and batch records for manufacturing of APIs under cGMP)

AMRI (Albany Molecular Research, Inc.), Chemical Development Dept, Albany, NY 1998 – 2010

Senior Research Scientist 0 – III / Group Leader

- Developed, optimized and streamlined several processes for the large scale production of multiples new chemical entities, including innovator drug candidates in projects originating from Pharma, Biotech, virtual Pharma, specialty Pharma and government agencies (NIH, NIDA); completed a successful transfer of over 25 processes for scale-up and manufacture of APIs under cGMP at the kilo-lab and pilot scale manufacture (including 9 projects as the lead bench chemist) to produce materials for IND-enabling toxicological evaluation and Phase I – Phase III clinical evaluation according to cGMPs, ICH and FDA guidance and regulations
- Lead an effective team of scientists to implement a wide range of customer projects; scientific direction and logistical management of multiple concurrent projects; coordinating role in several projects involving cross-functional teams (chemical development, QA/RA, GMP, engineering)
- Involved in a consulting role for troubleshooting late stage programs (registration/validation) and ongoing commercial production processes at AMRI's large scale manufacturing plant when needed
- Initiated the development of a core competency in crystallization within the Chemical Development Department and co-founded the Solid State group, which evolved into a thriving, distinct business unit; played a key role in leading and growing the Solid State group, building an integrated platform to smoothly transition from screening of salts and polymorphs to their practical scale-up and production under cGMP; spearheaded the acquisition and usage of PAT tools in crystallization process development and optimization to help monitor and control complex crystallizations in real time
- Generated proposals for customer projects; project management and coordination of interactions between project teams and customers through written correspondences, conference calls, written reports and on-site visits; authorship, review and editing of weekly/bi-weekly progress reports and comprehensive final project reports for over 120 projects
- Served as a Member of a multi-site Chemical Department Process Safety Committee

BINGIDIMI I. MOBELE, Ph.D.

The University of Kinshasa, Kinshasa, D. R. Congo (formerly Zaire)

1983–1988

Assistant Lecturer, Chemistry Department

Lectured on general organic chemistry, organic synthesis and reaction mechanisms and provided hands-on laboratory training to chemistry, pharmacy and medical school students

EDUCATION & TRAINING

1999 – Ph.D., Organic Chemistry (Methodologies/Total Synthesis/Biocatalysis and Chemo-enzymatic synthesis). The University of Akron, Akron, OH (USA). Research Advisor: Michael J. Taschner

1992 – M.Sc., Organic Chemistry (Chemo-enzymatic Synthesis). Mie University, Tsu-City (Japan). Research Advisors: Tamotsu Fujisawa and Makoto Shimizu

1988 – 1989 Visiting Research Fellow (Organic Chemistry). The Catholic University of Louvain, Louvain (Belgium, Leuven Campus). Research Advisor: George Hoornaert

1983 – Licentiate (M.Sc.), Chemistry. The University of Kinshasa, Kinshasa (D.R. Congo). Senior Thesis Advisor: Mukana-wa-Muanda

PATENTS

1. Polymorphs of 5-(3-(ethylsulfonyl)phenyl)-3,8-dimethyl-N-(1-methylpiperidin-4-yl)-9H-pyrido[2,3-B]indole-7-carboxamide and Methods of Use Therefor. WO/2009/129259; US2011/0184178; EP 2297145; JP 2011-518171
2. Synthesis of a Neurostimulative Piperazine. WO/2011/028548; US2010/046537
3. Dipeptidyl Peptidase Inhibitors. US2009/0275750; JP 2009-508873; CA 2622642; EP 1924567; CN 101360723
4. Polymorphs of Hydrochloride Salt of 5-(3-(ethylsulfonyl)phenyl)-3,8-dimethyl-N-(1-methylpiperidin-4-yl)-9H-pyrido[2,3-B]indole-7 carboxamide and methods of use thereof. US2009/040390; WO/2009/129191; CA 2721595
5. Crystalline Forms of Histone Deacetylase Inhibitors. US2008/051481; WO/2008/089436

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6. Catalytic Hydrogenation of Nitriles to Produce Capsaicinoid Derivatives and Amine Compounds, and Methods of Purifying and Obtaining Polymorphs Thereof. US2006/0047171; WO/2005/068414; EP1697303; CA 2551128

PUBLICATIONS/PRESENTATIONS/POSTERS

1. Process Development toward the Pilot Scale Synthesis of the Piperidine-Based Cocaine Analogue and Potent Dopamine and Norepinephrine Reuptake Inhibitor CTD 31,446. Mobele, B. I.; Kinahan, T.; Ulysse, L. G.; Gagnier, S. V.; Ironside, M. D.; Knox, G. S.; and Mohammadi, F. *Org. Process Res. Dev.* 2006, 10, 914-920
2. Process Development and Optimization for the Production of the Potassium Ion Channel Blocker ICA-17043 on a Pilot Scale. Mobele, B. I.; Venkatraman, S.; McNaughton-Smith, G.; Gibb, C.; Ulysse, L.; Lindmark, C.; Shaw, S.; Suto, M. J. Poster Presentation, *Chemical Development Symposium*, Albany Molecular Research, Inc. August 25 – 27, 2009
3. Process Development of SRT1720, a Potential Drug Candidate for Diseases of Ageing. El-Awa, A.; Disch, J.; Mobele, B. I.; Lunsmann, W. J.; Xie, R.; Perni, R.; Venkatraman, S. Poster Presentation, *Chemical Development Symposium*, Albany Molecular Research, Inc. August 25 – 27, 2009
4. Process Development of NSI-189 Phosphate. Mahmood, S.; Johe, K.; Mobele, B. I.; Venkatraman, S. Poster Presentation, *Chemical Development Symposium*, Albany Molecular Research, Inc. August 25 – 27, 2009
5. Process Development of SNX-5422 Mesylate. Duan, S.; Hong, X.; Smith, A.; Mobele, B. I.; Ulysse, L.; Lawless, L.; Locke, A.; Gargipati, R. S.; Venkatraman, S. Poster Presentation, *Chemical Development Symposium*, Albany Molecular Research, Inc. August 25 – 27, 2009
6. Indium Trichloride-Catalyzed Direct Cyanation of Benzylic Alcohols with Trimethylsilyl Cyanide. Venkatraman, S.; Mobele, B. I.; Ulysse, L. G.; and Lindmark, C. A. Poster Presentation, *Chemical Development Symposium*, Albany Molecular Research, Inc. August 25 – 27, 2009
7. Early Stage Chemical Process Development of DPP-4 Inhibitors SYR-322, SYR-619, and SYR-085. Reddy, J.; Sreenivasulu, G.; Garcia-Rubio, S.; Patra, D.; Sattelberg, T.; Gersten, E. C.; Paul, B. J.; Palmer, G.; Ulysse, L. G.; Mobele, B. I.; Reid, G. J.; Zhang, Z.; Wallace, M. B.; Gwaltney, S. L.; Stafford, J. A. GEN-059, 41st Western Regional ACS Meeting, San Diego, CA, October 9 – 13, 2007.
8. Purification, Polymorph Process Control, Crystallization Properties of Ilaprazole Form A and Highlights of Physical Properties of Various Other Forms of Ilaprazole. Mobele, B. I.; Lapina, O.;

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- Salsbury, J. S. Invited Lecture, *Ilaprazole Polymorph Summit II*, TAP Pharmaceuticals, Chicago, IL. May 23, **2007**
9. Approaches to Ilaprazole Polymorph Process Control. Mobele, B. I.; Ulysse, L. G. Invited Lecture, *Ilaprazole Polymorph Summit*, TAP Pharmaceuticals, Chicago, IL. April 20, **2006**
10. Capsavanil Process Development and Optimization. Mobele, B. I.; Meckler, H.; Ulysse, L. G.; Reed, D. P.; Uttley, M. D.; Littler, B. J.; Eastham, S. A.; Vogt, P. F.; Popp, K. F. Poster Presentation, *Frontiers in Drug Discovery Symposium*, Albany Molecular Research, Inc. October 6 – 7, **2005**
11. Crystallization and Polymorphism of Capsavanil. Isbester, P. K.; Elder, B.; Mobele, B. I.; Reed, D. P.; Ulysse, L. G.; Meckler, H.; Popp, K. F. Poster Presentation, *Frontiers in Drug Discovery Symposium*, Albany Molecular Research, Inc. October 6 – 7, **2005**
12. Indium Trichloride Catalyzed Deoxygenative Alkylation and Allylation of Benzylic, Allylic and Propargylic Alcohols. Mobele, B. I.; Duan, S.; Venkatraman, S.; and Dent, P. Poster Presentation, *Chemical Development Symposium*, Albany Molecular Research, Inc., Albany, NY. May 5-6, **2005**
13. Applications of the Enzymatic Baeyer-Villiger Reaction: Enantioselective Synthesis of (-)-Dimethyl Chorismate and (-)-Methyl Shikimate. Mobele, B. I.; Peddada, L.; Taschner, M. J. Abstract of papers, ORG 276, 216th American Chemical Society National Meeting, Boston, MA, August 23-27, **1998**
14. Studies Directed toward the Total Synthesis of Chorismic and Shikimic Acids. Mobele, B. I.; Taschner, M. J. Abstract of papers, ORG 157, 27th American Chemical Society Central Regional Meeting, Akron, OH, May 31 – June 2, **1995**
15. A Short Synthesis of (-)-(4*R*,5*S*)-Sitophilure Using the Regio- and Stereoselective Reduction of 3-Acyltetrahydrothiopyran-4-ones with Bakers' Yeast. Fujisawa, T.; Mobele, B. I.; Shimizu, M. *Tetrahedron Lett.* **1992**, 33, 5567
16. Enantioselective Reduction of 4-Oxo-3-tetrahydrothiopyranylacetates with Bakers' Yeast and Application to the Synthesis of a Prostaglandin Intermediate in Optically Pure Form. Fujisawa, T.; Mobele, B. I.; Shimizu, M. *Tetrahedron Lett.* **1991**, 32, 7055
17. Highly Enantio- and Diastereoselective Reduction of Sulfur-functionalized Cyclic Ketones with Bakers' Yeast. Fujisawa, T.; Yamanaka, K.; Mobele, B. I.; Shimizu, M. *Tetrahedron Lett.* **1991**, 32, 399

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PROFESSIONAL DEVELOPMENT COURSES

1. The Drug Development Process – Overview from Discovery to Commercialization. April 24-27, **2007** (UC Berkeley Short Course), San Francisco, CA.
2. Quantitative Process Understanding: a Critical Element of Successful Technology Transfer – A Structured, Novel and Proven Methodology Case Study. February 27, **2006** (TUNNEL Consulting). Pre-conference workshop prior to the proceedings on “Technology Transfer Summit” organized by IQPC, February 28 – March 1, 2006, Philadelphia, PA.
3. Secret of Batch Process Scale-up. March 23-25, **2005** (Francis X. McConville/FXM Engineering & Design), Albany, NY
4. ReactIR Training. February 27, **2005** (Mettler Toledo-AutoChem, 2005 Real Time Analytics User’s Forum), New York City, NY
5. Crystallization Training Seminar: Fundamentals of Batch Crystallization Design – A High-Tech Approach. February 24-25, **2003** (Mettler Toledo-AutoChem), New York City, NY
6. Parallel Synthesis and Experimental Design (DoE) for Rapid Process Development. October 2, **2002** (HEL, Inc.), Princeton, NJ
7. Practical Process Research and Scale-up. December 3-4, **2001** (Neal G. Anderson/Anderson Process Solutions), Albany, NY
8. Chemical Development and Scale-up in the Fine Chemicals Industry. June 14-16, **1999** (Scientific Update), Savannah, GA

HONORS/AWARDS

- **March 2009:** AMRI Level II Scientific Achievement Award recognition for “Development of a Novel, Scalable Route for the Preparation of RX-1001”
- **1994 – 1995:** Ohio Board of Regents Graduate Research Assistantship, The University of Akron, OH
- **1989 – 1992:** Graduate Research Scholarship, Japanese Ministry of Science, Education and Culture (MONBUSHO), Mie University, Japan
- **1988 – 1989:** Research Fellowship, The Catholic University of Louvain, Belgium



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MISCELLANEOUS

- Language proficiency: six languages, including English, French and Swahili (full proficiency); Japanese (limited working proficiency)
- Member of the American Chemical Society and Sigma Xi Society
- Peer reviewer for Organic Process Research & Development journal