

MICHAEL J. CHTOUROU

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RESEARCH SCIENTIST - QUALITY MANAGEMENT PROFESSIONAL

Proactive, results-oriented biopharmaceutical professional with 15 years' progressive expertise and responsibility in analytical research and drug product development leadership. Recognized with distinguished performance for biopharmaceutical characterization through instrumental analysis, leading to the establishment and proof of product quality. Project management with emphasis in cGMP laboratory start-up research and development, experimental design, and method validation. Thorough understanding of pharmaceutical quality and manufacturing processes. Superior GMP writing skills and communication.

Core Competencies

Analytical Research

- Analytical Method Validation Strategy - protocol, execution, report (ICH Q1,2,3 USP 21CFR211.165,194)
- Instrumental Analysis - Chromatography (HPLC) - Spectroscopy (UV, FTIR, MS, ICP, H-NMR)
- Physico-Chemical Analysis – (solubility, stability, excipient compatibility, structure elucidation)
- Bioavailability/ Pharmacokinetic characterization
- Reference standard characterization
- ICH Product Stability – biologic, pharmaceutical
- Analytical Instrument qualification, calibration, service, maintenance, repair
- Compendial methodologies – USP/ ACS/ FCC/ AOAC, EPA, ASTM, SM
- Analysis - Proteins, alkaloids, small chemical entities, active pharmaceutical ingredients, botanical drug products

Product Development and Validation

- Product Quality Planning – specification development, manufacturing process improvement, analytical technology
- GMP Technology Transfer
- CMC section documentation – IND/ AND submissions
- Drug manufacturing facility and equipment validation.

Quality

- Quality Assurance
- Quality Control
- Statistical Process Control
- GMP Document Control
- Regulatory Agency Audits
- CAPA - Investigations, Planned Deviations - Root Cause Analysis
- GMP Personnel Training and Skills Development (21CFR210, 211, 600)
- Laboratory Project Management (scope, cost, resource allocation)
- Contract Vendor Qualification
- CLIA/CMS Clinical Lab Certification
- Metrology Management
- Departmental Budget Planning
- Lab Facility Design

ACHIEVEMENTS

- Extensive analyte-driven analytical method development, optimization, validation (ICH Q1-3) - multi-mode, multi-detection, complex matrices, pure substances, stability degradant-indicating, and trace impurities (proteins, alkaloids, small chemical entities, hi-MW polymers). Mobile/stationary phase selection, sample pre-treatment, optimization of selectivity, resolution, capacity factor, and detectability. Submitted for pharmacopeial compendium review.
- New technology implementation – GMP laboratory deployment of automated analytical instrumentation increasing throughput and accuracy (HPLC, GC, TOC) in support of commercial drug product and manufacturing process quality.
- ICH stability profiling of APIs and recombinant proteins - Determination of degradation pathway and stabilizing formulation excipients. Accelerated stress testing (temperature, pH, photo/chemo oxidation).
- API Bioavailability/ Pharmacokinetic characterization - Oral-dose human clinical trials - analytical methodology design, optimization, validation (drug metabolite recovery in serum and urine), data interpretation. Clinical pharmacology summarized in PPI (patient product insert), FDA 21CFR201. \$10 million contract awarded.
- Topical transdermal formulation - designed topical API suspension formulation. Successfully tested through stability experiments and several human clinical trials (negative for contact dermatitis/ delayed hypersensitivity). \$3 million contract awarded.
- Product quality engineering/ development - manufacturing efficiency optimization, development and validation of analytical methods, product quality specifications, statistical process control for 15 API products.

- Technology transfer - successful transfer of quality procedures, methods, and equipment to GMP drug manufacturing facilities (Schering-Plough, et al).
 - International product qualification program - Spearheaded creation and implementation analytical testing and certification service supporting subsidiary international marketing (Asia, Europe, USA) - Developed and validated internationally standardized quantitative and qualitative chromatographic and spectroscopic methods for biomarkers in complex sample matrices (SEC, HPLC, UV-Vis, FTIR, MS, H-NMR). Quality certification enabled marketing efforts secure \$10 million in new accounts annually. Functioned as an independently-funded internal contract lab to subsidiaries.
 - Contract vendor qualification – Production raw material vendor selection and qualification.
 - Contract product specification testing – product matrix-specific contract lab selection and qualification (microbiological/ adventitious agents USP 21CFR 610.2-13; heavy metals contamination by ICP-MS/ RCRA; pesticides/ toxins; DNA contamination – GMA).
 - Clinical laboratory registration - CMS/ CLIA (Centers for Medicare & Medicaid Services/ Clinical Laboratory Improvement Amendment) Successfully obtained certification by meeting federal documentation, personnel training, and facility requirements. Documented quality functions into cGCP/cGLP compliant SOPs.
 - Senior management team member. Multi-disciplinary and international project team collaboration. Excellent interface with high-profile clients, scientists, regulatory officials.
 - Safety Committee chairman.
 - Employee of the Month, June 2004, Unigen Pharma
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PROFESSIONAL EXPERIENCE

Unigen Pharmaceuticals Inc., Broomfield, Colorado **Analytical Research & Development Scientist**

2000 to 2004

- Extensive API analytical method development in conjunction with new product, market expansion, and consequent regulatory requirement evolution (21CFR211.165,194, ICHQ1-3, EPA/RCRA guidelines).
- New product quality - production quality optimization, design validation, stability testing, development and validation of analytical methods, product quality specifications, statistical process control for 15 API products.
- Product certification program - Developed and validated internationally standardized chromatographic and spectroscopic methods for complex sample matrices (HPLC, SEC, MS, H-NMR, UV-Vis, FTIR).
- Accelerated ICH stability characterization - elucidation of API degradation pathway and stabilizing excipients.
- Bioavailability/ Pharmacokinetic characterization – USP/ ICH Q1-3.
- Contract lab method qualification – selection and qualification of contract labs by product matrix-specific testing (USP microbiological; heavy metals contamination by ICP-MS/ EPA-RCRA; pesticides/ toxins; DNA contamination – Genetically Modified Organism, GMO).
- Analytical research & development support - subsidiary company operations. Timely, high quality delivery of services.

Quality Manager

- Led team of analytical chemists engaged in product quality and analytical R&D support.
- Quality Assurance and product release certification.
- Product quality planning – specification development and manufacturing process improvement. Sustain regulatory compliance to expanding product markets by developing new analytical methods for new specifications.
- CAPA investigation and resolution of quality events, planned deviations, and customer complaints.
- Contract product quality testing – laboratory selection, product matrix-specific test validation, auditing (USP microbiological/ adventitious agents; heavy metals; pesticides/ toxins; DNA contamination/ GMA).
- Transfer technology to cGMP pharmaceutical manufacturers (HPLC equipment, analytical methods, manufacturing SOPs).
- Qualification of analytical instrumentation (IQ/ OQ/ PQ). Extensive troubleshooting, repairing, and maintaining analytical instruments (HPLC/ MS, GC, spectrophotometers).
- Department budget management.
- Personnel proficiency training, mentoring, skills development.
- Metrology management.
- Clinical laboratory management - CMS/ CLIA certification

Associate Manager

2004

Amgen Quality Analytical Laboratories / Lancaster Laboratories, Longmont, Colorado

- Supervised multi-department GMP contract lab team of 35 quality analysts (Analytical Chemistry, Biochemistry, Cell Biology, Immunology, Microbiology, Raw Materials). Supported Aranesp and Kineret production.
- Client-based method and SOP training, analytical data review and approval, client mediation.

- Developed and implemented training documentation to monitor and improve lab team performance.
- Exceeded contract performance requirements for lab team accuracy, quality, and productivity.
- Excellent client service performance recognized and praised by Amgen management.

Quality Analytical Protein Chemist

1996 to 1998

Amgen Colorado, Inc., Boulder, Colorado

- Analytical support – clinical product, process development, microbial manufacturing plant validation.
- QC Protein Chemistry method transfer leader, Longmont Epogen plant start-up.
- Emergency response commercial product lot release protein chemist (Epogen and Neupogen), Amgen Colorado site (Longmont pre-validation phase).
- Special projects consultant - Analytical Resources. Quality department chromatography proficiency trainer.
- Analytical instrumentation selection and qualification.

Protein Chemist - Quality Analytical Chemistry, Analytical Research & Development

1990 to 1996

Amgen Thousand Oaks

- cGMP Department Start-up - Quality Control Protein Chemistry. 21CFR-201 compliant lab for Amgen's multi-product, international biologic manufacturing.
- Analytical method transfer, optimization, and robustness revalidation. Protein reference standard characterization and validation.
- Analytical support – commercial and clinical products and formulation excipients (Epogen, Aranesp, Neupogen, Infergen, BDNF, GDNF, KGF, MDGF, CIFN, SCF, IL-1ra, IL-2, IL-3, NT-3).
- Analytical support – product stability, process development, manufacturing validation. Product identity/ purity [N-terminal amino acid sequencing, RP-HPLC (oxidation/reduction, peptide mapping-tryptic/red-carboxymethylation), IE-HPLC (formyl-methionine), SEC (aggregation), USP <621>] - commercial and clinical products.

Quality Assurance and Regulatory Affairs Activities - Amgen

1990 to 1998

- Extensive project collaboration with manufacturing validation group. Validated and implemented automated TOC analysis at Amgen. TOC research was critical to commercial product microbial plant CIP system optimization and validation. Wrote TOC validation report submitted to FDA, assisting procurement of commercial license (Neupogen, 1992-1993).
- Department Audit representative – FDA/ International Regulatory Agency inspection. My jurisdiction never cited.
- Analytical instrument qualification strategies (IQ/ OQ/ PQ) – wrote Amgen's first (TOC, HPLC).
- Laboratory technology selection/ procurement – HPLC, GC, TOC.
- Quality laboratory procedure revision and harmonization – Global-scope manufacturing site.
- Proficiency trainer (chromatographic and compendial methodologies: USP, FCC, ACS, EP, BP, JP) – quality, process development, manufacturing validation personnel.
- Electronic GMP data management program development, validation, improvement (raw data reduction and statistical analysis).

Supervisor, Organic Extraction laboratory

1989 to 1990

Alsea Brown Boveri Environmental, Camarillo, California

- Supervise extraction lab operations. Oversee isolation and analysis of environmental pollutants.
- Solid and liquid sample matrices. EPA, SM, AOAC, ASTM, NCASI, USP methodologies.

Stock Broker/ Financial Advisor

1999 to 2000

Prudential Securities Inc., Denver, Colorado

- Securities sales, trading, and portfolio management (stocks, bonds, mutual funds).
- Registered with Securities Exchange Commission (SEC), National Association of Securities Dealers (NASD), and the Colorado Insurance Commission.
- Held Series 7, 63, 65 Securities licenses and Colorado State Life & Health Insurance licenses.

Mechanical Engineering Contractor

2005 to Present

Chateauroux Studio, Boulder, Colorado

- Contractor, Engineering and Manufacturing Technology. CNC machine tool service and repair, reconditioning, re-engineering, and sales. Prototype engineering and manufacture. Supporting aerospace and petroleum industry manufacturing.
- Fine Art Photographer - studio, landscape, advertising, conceptual. Complete in-house film to digital workflow. Adobe Photoshop CS2, PhotoKit Sharpener Pro, Nik Multimedia Dfine.
- Website Development and Graphic Design – XHTML, PHP, Adobe Flash, Dreamweaver, Illustrator.
- Fine Art Sculpture - marble and bronze. Commission and free-lance, maquette to life-scale.

EDUCATION

B.A. with Honors, Biochemistry and Molecular Biology, University of California, Santa Cruz
1989

Graduate Program, UCLA Graduate School, Molecular Biology (Pharmaceutical Technology)
1993

MS/ PhD Program, Biomedical Sciences, Loma Linda University Graduate School,
Schools of Medicine and Dentistry (MCAT scores at 99.99th Percentile)
1995-1996

PATENTS

- *Identification of free-B-ring flavonoids as potent COX-2 inhibitors.*
US Patent pending, March 1, 2002 (Application No. 10/ 091,362)
- *Isolation of a dual COX-2 and 5-lipoxygenase inhibitor from Acacia Sp..*
US Patent pending, March 22, 2002 (Application No. 10/ 138,932)
- *Formulation of a mixture of free-B-ring flavonoids and flavans as a therapeutic agent.*
US Patent pending, April 30, 2003 (Application No. 60/ 377,168)
- *Formulation with dual COX-2 and 5-lipoxygenase inhibitor activity for use in the prevention and treatment of cognitive decline and age-related memory impairments.*
US Patent pending, Sept. 2, 2003
- *Formulation of Dual COX-2 and 5-Lipoxygenase Inhibitor for Mammalian Skin Care.*
US Patent pending, Feb, 2004 (Application No. 10/ 817,330)
- *Inhibition of carbohydrate-induced obesity with a defined plant extract.*
US Patent pending, Feb. 6, 2003 (Application No. 60/ 450,922)
- *Polycosanol from Ericerus Pela wax*
US Patent allowed, Jan 31, 2003 (Application No. 10/ 356,676)
- *7-Hydroxy Chromones as potent antioxidants.*
US Patent pending, May 3, 2002 (Application No. 10/ 138,932)

PRESENTATIONS

- "Developing novel nutraceutical and cosmetic ingredients from aloe chromones"
6th annual International Aloe Science Council Scientific Seminar, Sept. 13-14, 2002
Las Vegas, Nevada
- "European Union-directed trace analysis of aloin in food and beverages: method development and validation"
7th annual International Aloe Science Council Scientific Seminar, Oct. 16-19, 2003
Las Vegas, Nevada
- "Free-B-ring flavonoids and flavans act as COX and LO dual inhibitors for improving mobility and physical functions of arthritis"
1st International Conference on Polyphenols and Health, Nov. 18-21, 2003
Vichy, France
- "TOC Measurements for the Validation of CIP Processes in the Pharmaceutical Industry"
Pittsburgh Conference, 1993