

Justin C Giaquinta, PharmD

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Key Skills

- **Clinical Research Expertise:** Advanced knowledge of ICH-GCP, study design of Phase I-IIIb trials.
- **Leadership/Administration:** Experienced successfully managing large and small teams, direct reports.
- **Clinical Pharmacotherapy:** Therapeutic areas - gene therapy, hematology, oncology, immunology, pulmonology, GI, genetics, rare diseases, neurology, cardiology, infectious diseases.
- **Communications:** Mastery of verbal and written communications, experienced presenter/lecturer.
- **Operations:** Policy/SOP development, budgeting, departmental representative, projects.
- **Medical/Technical Writing:** Simplifying complex medical literature, study data, protocol design, and tailoring to specific audiences (medical, nursing, pharmacy, layperson).
- **Regulatory Affairs:** Experienced in FDA, DEA, sponsor audits, IRB/IEC, CAPA responses, inspections.
- **Process Engineering:** Problem solving and cost/time-saving deliverables using Lean 6 Sigma principles
- **Computer Proficiency:** Windows, MS Office Suite power user, Computer Programming hobbyist.

Work Experience

Clinical Research Pharmacist Manager - Investigational Drug Services

2017 – Present: University of Florida Health Shands Hospital, Gainesville, FL

- Manage operations and dispensing on 300 protocols (clinic and hospital - sponsored, cooperative group, investigator-initiated trials).
- Strategize with investigators, study coordinators, statisticians to help develop and implement multidisciplinary research studies conducted according to protocol and sponsor-driven requirements.
- Develop and maintain policies and regulatory compliance on a site and protocol-specific basis for inspection readiness from regulatory bodies, sponsors, and CROs.
- Author succinct Protocol Education Sheets for interdisciplinary research teams to train on protocols using Protocols, Pharmacy Manuals, Investigator Brochures.
- Prepare Executive Summaries for Pharmacy and Clinical Research Center administration – capital, salary, FTE requests using service revenue and expense metrics.
- Prepare estimates and monthly billing, and manage fiscal year budgets and fee structures.
- Train and credential new hire pharmacists, residents, technicians on research practices.
- Oversee budgeting, SQV, SIV, informatics builds, education for medical, pharmacy, and nursing staff.
- Meet with CRAs, CTMs, sponsor/FDA auditors, and other key stakeholders (COG, ETCTN, NIH) to ensure regulatory compliance and data integrity.
- Lead for research software: Vestigo, OnCore CTMS, DicksonOne temperature monitoring, Simplifi797.
- Experienced with multiple IRT and EDC systems
- Lead compounding pharmacist including gene therapies (BSL-1 and BSL-2) and non-sterile to sterile
- Developed software-based workflows: protocol and credential tracking, efficiencies, forms, checklists.

Clinical Veterinary Pharmacist

2016-2017: University of Florida College of Veterinary Medicine, Gainesville, FL

- Managed electronic formulary consistency and safe naming conventions
- Overhauled anesthesia narcotic process for case-based narcotic reconciliation and accountability
- Lead compounding pharmacist – non-sterile and sterile

Clinical Adjunct Professor

2015-2021: University of Florida College of Pharmacy, Gainesville, FL

- Lecturer for Dosage Forms, Doctor of Pharmacy curriculum, “Principles of Stability and Compatibility”
- Developed quizzes and test questions for students and assisted in online discussion forums

Central Pharmacy Operations Manager

2014-2016: University of Florida Health Shands Hospital, Gainesville, FL

- Managed team of 50 people: 15 pharmacists, 2 tech coordinators, and 33 pharmacy techs.
- Human resource utilization: hiring, evaluations, corrective actions, terminations.
- Managed new policy and SOP development. Annual review of 35+ policies for Central Ops.
- Advanced regulatory compliance from 77/125 to 123/125 for Board of Pharmacy inspection
- Lead operations in USP 797 clean rooms (including hazardous chemotherapy) and a USP 795 non-sterile compounding/repackaging area
- Created and administered competency tests for various areas of pharmacy via online modules
- Preceptor and administrative advisor for pharmacy students on hospital rotation
- Committees: Pharmacy & Therapeutics, P&T/Ops, Nursing-Pharmacy Ops, Network Cancer Committee, New Tower Development.

Inpatient Hospital Pharmacist

2011-2014: University of Florida Health Shands Hospital, Gainesville, FL

- Inpatient pharmacist: Hazardous and non-hazardous IV therapy, TPN, OR, Investigational Drugs Service, Med-Surg, ICU, and BMT/oncology satellite
- Experienced with Epic Willow and Beacon, Omnicell ADS, OCRA, Centricity EMR, Abacus
- Committees: Pharmacy Strategic Planning Committee, UF College of Pharmacy Curriculum Committee

Clinical Ambulatory Pharmacist

2011-2011: Ambient Healthcare, Orlando, FL

- Home health care clinical pharmacist, supervising compounding in a USP 797 compliant clean room.
- Adjusted therapies based on clinical picture and PK via physician-approved scope of practice
- Therapies included biologics, chemotherapy, inotropics, antibiotics, and TPN.

Education

2007-2011: University of Florida, College of Pharmacy, Gainesville, FL

- Doctor of Pharmacy (PharmD)

2005-2007: Santa Fe Community College, Gainesville, FL

- Associate’s Degree – Pre-Pharmacy

Research, Publications, Presentations

- Comparison of Prophylactic Intravenous Antibiotic Regimens After Endoprosthetic Reconstruction for Lower Extremity Bone Tumors: A Randomized Clinical Trial. *JAMA Oncology*
- Impacts of Preservative-Free Albuterol in Status Asthmaticus. *Presentation to P&T Committee*
- Implementation of the CTMS-Vestigo Interface. *Presentation to UF Clinical Research Committee*