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PROFESSIONAL SUMMARY

Senior Pharmaceutical R&D Executive, Technical, Quality and Regulatory Expert with extensive experience in generics and branded drug product development and market launch. Directed development and execution of 225+ new products leading to 170+ regulatory submissions and 105+ regulatory approvals/launches with several first-to-file opportunities. Strong leadership skills in mentoring and coaching scientists and chemists for "first to file" / high barrier products development, ANDA/ NDA filings, approval and launch in US market. R&D Lead Facilitator in establishing regulatory and quality systems for filing drug products in other global markets such as Canada and Europe. Experience in developing/ testing of generic products in India and filing in the US. Comprehensive knowledge in all major aspects of pharmaceutical business. Experienced technical leader in establishing robust and efficient systems within R&D and corporate divisions. Systems include SOPs, policies, guidelines, technical records, enterprise resource planning software (SAP), quality databases/ matrices (respective software), product development reports, investigations, patient complaints and CMC documents. Synergized challenging product development (highly potent, difficult formulation, cytotoxic, unconventional dosage forms) with R&D pilot plant, analytical laboratory and manufacturing capacity state-of-the-art expansions. Consistent and dedicated scientist/supervisor with efficient qualities in speed, accuracy, accountability, communication, teamwork, and flexibility to meet current FDA and market/ business requirements. Key competencies include:

AREAS OF EXPERTISE & CORE SKILLS

- Strategic Thinker for Optimal R&D Pipeline
- Regulatory & Compliance excellence
- Risk Management & Quality
- Pharmaceuticals – small and large biologics products manufacturing, analytical/ QC laboratories testing
- Critical Quality Attributes (CQA)
- Project Management & Planning
- Business Units Integration
- Applied Scientific & Technical Skills
- Research & Development
- Critical Material Attributes (CMA) & Critical Process Parameters (CPP) of all product components

QUALITY AND REGULATORY EXPERTISE

Quality and regulatory related experience gained at the companies described below by direct involvement in overall Quality, QA, Audits, cGMP, SOPs, Investigations for planned and unplanned Deviations, Change Controls, FDA Compliance, PAI and address FDA comment letters when worked at all the companies. As a scientific and technical advisor/ veteran by education & hands on training, provide services to solve, investigate, trouble shoot any quality related issue related to Products Manufacturing, Packaging, Analytical, Facility/ Equipment, Commercial Products complaints and investigations with special emphasis on Data Integrity reviews and Audits. Products include small and large molecules (biologics) and drug device combination.

ANALYTICAL, MANUFACTURING & CLINICAL EXPERTISE

- General: Review and approve:
  - Raw material [excipients] testing per certificate of analysis – USP/ NF/ vendor / in-house. Standard vendor test(s) method(s) – verification and qualification
  - Active pharmaceutical ingredient per certificate of analysis – testing – USP/ vendor/ in-house. Method development and validation.
  - Finished product/ dosage form – orals and non-orals: test methods development and validation. Method development and validation.
  - Stability indicating methods – development and validation; accordingly set specifications for controlled room temperature and accelerated conditions. Stability Reports: Predict/ propose - shelf-life/ expiration dating.
  - Set specifications for impurities [process/ degradation] per raw material, in-process, finished product, FDA / ICH guidelines and clinical relevance based on dose per day. Particle size, moisture, LOD, organic volatile impurities, genotoxic impurities.
  - Microbial testing: related to sterile products – injectable, ophthalmic, etc.
  - Laboratory deviations: Planned / un-planned and related investigations

- Method transfers: Analytical R&D to QC or company second site or company site to CMO / CRO or CMO/ CRO to company site, as applicable. COA updates – commercial batch release / reduced testing, as applicable
- FDA comment letters: Address methods and test data explanations presented in reports and resolutions for identified gaps.

- Audit & investigate for data integrity from Investigations / CAPA & internal audits.

- Remediation for Compliance/ cGMP issues:
  - CAPA & Investigations – writing and review.
  - Related protocols & reports writing & review.
  - Related SOPs revision & write/ review missing SOPs.
  - Training, as required to meet compliance for department(s) & site.

- Prepare, review and approve:
  - API / drug product manufacturing masters (small and large molecules), validation protocols, DOE development reports and validation reports including continued process verification protocol (CPV) and execution. Provide training to scientists, chemists and operators.

  - CMC documents and respective modules for ANDA, IND, NDA & BLA

- Review pre-clinical, clinical, bioavailability, bioequivalence, pharmacovigilance related protocols, data analysis and reports and annual product quality reports (APQR)

- Customer and patient complaints handling / investigation preparation:

  - Track complaints receipt, investigation and on time closing of the complaints including trend analysis
  - Support root cause analysis of the complaint as applicable and facilitate CAPA

- Pharmacovigilance: Review post ANDA, IND, NDA and BLA filed products before and after commercialization; Mitigate risks from adverse events related to safety and efficacy based on purity and impurities profile monitoring of the drug product and comply with FDA ICH-M7, Q7 and Q11 guidance; review clinical relevance and impact following latest industry trends and practices

- Develop and execute:

  - Continued process verification (CPV) and continued quality verification (CQV) programs for critical process parameters (CPP) identification and respective critical quality attributes (CQA)

PROFESSIONAL EXPERIENCE

SANKAV PHARMACEUTICALS LLC, Chester, NJ **Sept 2016 to Present**
Chief Executive Officer, President & Founder
Founded SanKav Pharmaceuticals to provide consulting services to pharmaceutical, biotechnology and nutraceutical companies in USA and abroad. Expertise in business development, R&D, technology/ manufacturing, testing, quality, audits, regulatory, process validation and commercialization. The website provides details: www.sankavpharma.com. Scientific Advisor to Investment Firm(s). SanKav is constantly seeking collaborating opportunities in the biologics, nutraceuticals, high-barrier generics, biosimilars and brand products including biotechnology products research and development, comprehensive analytical testing and characterization, file with US-FDA and get approval. SanKav has established relationships with growing companies in US and India. Eventually, market the product(s) with other distribution companies in US and other countries.

Recently, SanKav has purchased a new building (~29,000 SF) in Morris County NJ. Set-up is in-progress for the new state of the art analytical/ quality control laboratories, cell culture lab, microbiology laboratory, research labs and cGMP clinical/ commercial manufacturing plant to support the niche market of biologics (antibodies, antibody drug conjugates, cell and gene therapies, etc.), injectables, ophthalmic, topicals and other oral and non-oral controlled release dosage forms products. SanKav is conducting new product development activities as a CRO and CMO for other pharmaceutical company clients.

Completed technology upgrades, validation (cleaning, process & continued process verification program) and regulatory /quality compliance projects assessment and remediation at a global pharmaceutical company located in Europe. Consulted in data integrity resolution and remediation activities related to oral dosage forms, aseptic manufacturing and testing of Sterile Injectables Medications including Blow Fill Seal technologies, latest glass vial and ampoule filling technologies, and freeze drying of commercial products in India and Taiwan.

Consulted for FDA 483's responses and remediation for an oncology center and compounding pharmacy (workload of ~300 prescriptions per day) affiliated to many hospitals for intravenous infusions therapy and drug delivery systems.

Gained valuable experience in quality and technical improvement, BLA filing, pre-approval inspection (PAI) readiness of a novel FDA Breakthrough Therapy designation oncology drug product that is an antibody-drug conjugate infusion drug product. Technical review of product development, scale-up, process validation and performed risk assessment of critical material attributes (CMA)/ specifications for process and degradation impurities and critical process parameters (CPP) linked to the respective critical quality attributes (CQA) for all materials and components of the antibody drug conjugate product.

Reviewed, consulted, and advised a fast-growing pharmaceutical company client for commercial products analytical and quality control laboratory records and data to address FDA warning letter gap assessment for remediation purposes. Also, provided support and training for the quality systems including but not limited to laboratory investigations, change controls, deviations, patient complaints and CAPA.

Recently was engaged in a public company to solve their commercial product(s) manufacturing batch failures. One of the products is a topical ointment. We investigated and troubleshooted the issues from R&D and technical perspective and confirmed the root cause. The company is working on the process validation and continued process verification (CPV) of their key products portfolio.

OPERATIONS & QUALITY SYSTEMS IMPROVEMENT EXPERTS **April 2020 to Present**

Conducted technical, scientific and quality assurance audit review of analytical and quality control records, certificate of analysis, methods, chromatographic (HPLC/UPLC/ GC) Empower data, TLC, all other wet chemistry testing, physical characterization, compendial (USP/ NF) identification tests, particle size testing, residual solvents, elemental analysis, laboratory notebooks, instrument logbooks, reference standards and day to day samples of raw materials, intermediates and finished dosage form (oral tablet, capsule, liquids, etc.) testing. Reviewed records of many retrospective and prospective batches laboratory data for gap assessment as related to the FDA warning letter response and commitment to FDA provided by the pharma client.

Reviewed and provided both technical and quality related comments to the laboratory investigations reports for prospective commercial batches prior to QA release for shipment to market. The cGMP batches included FDA submission batches and commercial batches.

Provided detailed training in quality systems such as Change Control for the respective departments of the company. Worked together with the company quality team, consultants, and advisors on the project at the client company manufacturing site and participated in the patient complaints and investigations reporting related to critical and major issues that were discovered during the third-party assessment. Quality systems support included but not limited to CAPA (corrective and preventive actions), manufacturing deviations, laboratory investigations, training, SOPs and customer/ patient complaints. The overall project was supported full time and on-site for more than 3 months.

QUALITY EXECUTIVE PARTNERS, INC. **Nov 2018 to Present**
Partner
Serves as a technical subject matter expert on quality and regulatory compliance consulting projects to pharmaceutical, biologics, and medical device companies.

- Completed technology upgrades, validation including continued process verification (cleaning & process) and regulatory /quality compliance projects assessment and remediation for new commercial and legacy products at a global pharmaceutical company located in Europe.

- Currently working at a biotechnology company as a subject matter expert in FDA/ ICH compliance and assisted in BLA submission, Quality and Technical Improvement Program including PAI readiness for a novel FDA Breakthrough Therapy designation oncology drug product. It is an antibody-drug conjugate infusion drug product.

LACHMAN CONSULTANT SERVICES, INC. **April 2018 to August 2019**
Senior Associate

Consulted in data integrity resolution and remediation activities related to oral dosage forms, aseptic manufacturing and testing of Sterile Injectables Medications including Blow Fill Seal technologies, latest glass vial and ampoule filling technologies, and freeze drying of commercial products in India and Taiwan.

Consulted for FDA 483's responses and remediation for an oncology center and compounding pharmacy affiliated to hospitals for intravenous infusions therapy and drug delivery systems. It included remediation activities to support new systems of quality and business operations. Drug products of small and large molecules chemotherapy drugs, antibiotic drugs and respective diluents related to intravenous infusions therapy. It included the aseptic and affiliated areas of ISO 7, ISO 8, facility/ rooms, warehouse, ISO 5 equipment/ booths, media fills, environmental monitoring, microbiological tests (in-house and laboratory) and personnel qualifications and training.

KASHIV PHARMA, LLC., Bridgewater, NJ **[Now Kashiv BioSciences]** **Jan 2011 to Aug 2016**
Chief Operating Officer & Executive Vice President of Research & Development
Co-founded and setup the new privately held / funded company and helped in recruiting executives and management staff of formulation R&D, analytical R&D, Quality and Technical Services/ Operations. Formed a team of fresh pharmaceutical graduates and experienced scientists in formulation, analytical, technical services, manufacturing, operation, quality and regulatory functions. Kashiv is set-up to develop 505b2/ NDA projects, support third-party company research, manufacturing and technology platforms (in-licensing and out-licensing).

- Purchased and qualified state of the art analytical laboratories, pre-formulation & chemistry laboratory, pilot plant instruments and equipments to develop several dosage forms/ drug delivery platforms.
- Created systems for GLP and cGMP SOPs, guidelines and policies for efficient functioning. Mentored Quality Assurance and Management Staff for all quality and compliance related matters including but not limited to Change Controls, Deviations, Investigations, CAPA and Cleaning Verifications/ Validations.
- Company followed FDA, OSHA, state and other federal regulations.
- Served as an advisor and reviewer of several complex pipeline generic projects product development [pre-formulation characterization, formulations research, process optimization and analytical strategic tests] sponsored by Amneal Pharmaceuticals and filed with FDA in 2011, 2012, 2013, 2014, 2015 and 2016. Few high value products will be filed in 2017.
- Setup and qualified commercial scale equipment [fluid-beds/Wurster, film coaters, instrumented tablet presses, special encapsulator, nano-mills, soft gel encapsulator, hot melt extruders, extruder with spheronizer, special dose units assembly linen (drug-device) with blister packaging and vision systems].
- Several complex products have been FDA approved and an authorized generic product, Yuvafem (brand: Vagifem of Novo Nordisk) was launched in first quarter of 2017. Others are launched and will be launched in the near future. Finally, another complex product, first generic of NuvaRing is FDA approved as of Dec 2019. Remaining products are in the FDA review cycle.
- Provided scientific, technical and regulatory support for proof-of-concept bio-studies program for 505(b)2 projects in pipeline up to IND filing. One 505(b)2 product is optimized for market formula, clinical studies programs and was expected to file NDA in 2018.
- Transitioned /re-located Kashiv operations and site from Piscataway, NJ to Bridgewater, NJ (Ex State of Art Sanofi/ Aventis Site) including all facility, equipment, instruments, qualifications, etc.
- Facilitated DEA analytical registration completion for Piscataway, NJ. Applied and received DEA registrations for analytical, research and manufacturing at Bridgewater, NJ (NJ State and Federal registrations).
- Site is cGMP compliant. Site was inspected by European Union Qualified Person (QP) in 2014. Kashiv was successfully FDA inspected in 2015 and 2016 without any observations.

Pharmaceutical R&D Consultant **2009-2010**
Reviewed new generic potential products for 2010 and beyond. Prepared budget and ROI for key projects. Registered a new company in California. Presented business proposals to pharmaceutical companies and investors. The new company goal was to develop formulation & process of products, analytical development & validation, contract research & manufacturing for third-party, scale-up & process validation, ANDA/ NDA filings documentation.

Worked with Amneal Pharmaceuticals, LLC of NY as new product R&D advisor. Developed and filed a first to file generic drug product. Researched new commercial buildings for a new R&D facility that includes, pilot plant, analytical laboratories, warehouse, etc. for expansion.

WATSON PHARMACEUTICALS, INC., Corona, CA **[Later Actavis then Allergan]** **2008 -2009**
Vice President, Generics Research & Development
Reported to Senior VP and Global R&D Head. Managed multi-million dollars generic R&D portfolio from new product selections to approvals/launches with focus on moderate to high barrier ("niche") products. Directed staff of 120 in R&D, portfolio and project management, product development (internal and external), R&D operations, biopharmaceutics, and regulatory affairs in submissions and technology.

- Reviewed new generic project files in development, including oral contraceptives, hormone replacement therapy, high-barrier tablet and capsule products, controlled and modified release drug products, and narcotic scheduled drug products.
- Ensured that adequate analytical support was provided to the development of special drug delivery products for feasibility (product selection), local execution and working with external partners and contract labs.
- Studied strengths of team members in pharmaceutical and analytical departments; mentored and provided tools for training directors, supervisors and team leaders, scientists and chemists; identified deficiencies to improve efficiency in formulation and analytical methods developed per FDA's latest Question Based Review process.
- Worked with senior management and HR to re-organize and conducted significant reduction in force; formed a special team of chemists that provided analytical support to pre-formulation and troubleshooting activities during development of projects from other global R&D centers.
- Participated in global R&D quarterly meetings that included R&D key function heads, finance and business development.
- Streamlined regular meetings and discussions within R&D and outside R&D to improve R&D functions by working with project management
- Created R&D capital purchases budget of $4 million for 2009 including new laboratory state-of-the-art instruments, equipment, detectors, and software.
- Ensured that adequate funds were allocated for API and biostudies for site projects by working with purchasing, biopharmaceutics, finance, and operation planning teams.
- Worked with new product selection committee to select new drug product candidates for pipeline, mostly oral dosages but also evaluated other drug delivery route candidates.
- Introduced new drug products in R&D program and executed them based on FDA's design space protocol, and pilot biostudies leading to successful pivotal bio-equivalency.
- Supervised formulation technical team leaders to review patents for formulation and process selections; also worked with legal department
- Setup close technical communications between pharmaceutics and formulation as well as biopharmaceutics and analytical development teams to effectively produce successful IVIVC (in-vitro in-vivo correlation) data for lead formula selection.
- Monitored batch size scale-up process from pilot size of lead formula-process to production equipments by efforts of technical services / operations, manufacturing and R&D scientists.
- Worked with a management team of key function directors for execution of new drug product developments (formula, process and analytical methods), successful bio / clinical studies, filing of CMC documents (quality overall summary, PDR, ADR) via regulatory affairs to FDA.
- Supervised and directed formulation and analytical departments to work with regulatory affairs for responding to deficiency letters from FDA per required timelines.
- Supported R&D team to work with technical operations, manufacturing, and ARD/ quality control labs for smooth execution of 3 commercial scale process validation batches of new products.
- Participated in weekly meetings to manage progress of projects from four R&D centers (3 in the U.S. and one in India).

BARR LABORATORIES INC., Pomona, NY **[Now Teva Pharmaceuticals]** **1993 - 2008**
Senior Director, Research & Development (2005 -2008)
Reported to Global EVP of R&D and managed 40 Formulation Scientists, Senior Scientists, Principal Scientists, Technicians, Managers, Associate Director and Directors with focus on development, successful bio/clinical studies, approval and launch of new products on time to meet corporate goal and objectives.

- Continued to carry out responsibilities and assignments as mentioned during Director position; Monitored and helped on projects under other Team Leaders in R&D
- Evaluated new projects with emphasis on new actives from new vendors and new excipients or packaging components not previously in any marketed drug product.
- Supported safety and engineering teams to meet EPA requirements for all new projects.
- Worked with engineering, manufacturing, technical services, and cleaning validation to purchase new equipment, setup, IQ/OQ/PQ, and executed / established new processes at GMP area.
- Continued to work with Barr's Controlled Substances & Security Team to comply with DEA requirements for all new projects.
- Supported Clinical Operations team for existing project clinical supplies for Phase 2 and 3, and new NDA projects for activities required by R&D team for formulation / process development, manufacturing, packaging, SOPs, and operation systems.
- Worked with cross functional departments to effectively manage inventory of existing common and new materials via ERP computer systems (GMP and non-GMP); Implemented trials plant setup for R&D in SAP.
- Developed systems, policies, guidelines, SOPs and documents in R&D to effectively train personnel to carry out daily, GLP and GMP jobs, and coordinate with other departments.
- Worked with outside contractors, QA, R&D QA, and project management to develop, manufacture, package, and ship new drug products - including unconventional drug delivery systems.
- Involved with business development team for due diligence of new product and processes at outside companies / corporations.
- Worked with Regulatory Affairs and Quality Compliance teams to address any deviations, regulatory submission items and reply to FDA comment letters and pre-approval inspection.
- Worked with Technical Services and Process Validation teams to scale-up and provide support to launch new products.

Director, Research & Development (2002 – 2005)
Associate Director, Research & Development (2000 – 2002)

- Developed, scaled-up, and launched many ANDA (100+) and NDA (15 to 20) products.
- Developed IR products in 2 weeks to 3 months and ER products in 3 to 6 months thereby reducing development cycle time by 25% - 50% using planned / statistical approaches.
- Guided scientists and Scientific Affairs / Biopharmaceutics in evaluating products prior to dosing for bioequivalence or clinical studies.
- Created and evaluated analytical methods / data during development work.
- Directed R&D product development operations including inventory control, all commercial grade raw materials/ intermediates, API/ drugs, excipients and packaging components specifications (process impurities and degradants) and quality attributes, document control, and manufacturing and packaging of new products to launch stages.
- Worked with Technical Affairs, QC, Analytical R&D, and QA to accomplish test and release of all raw materials, actives and excipients for all R&D projects.
- Created, reviewed and approved change controls for specification sheets, test methods, manufacturing processes, packaging, new equipment and transfers through electronic system.
- Created, reviewed, approved and trained departmental and company SOPs for R&D operations.

Manager, Research & Development (1999 - 2000)
Principal Scientist, Product Development (1998 - 1999)
Team Leader and TGL, Product Development (1996 - 1998)
Technical Group Leader, Product Development (1995 - 1998)
Formulation Scientist, Product Development (1993 - 1995)

WYETH-AYERST, AMERICAN HOME PRODUCTS, Pearl River, NY. **1992 – 1993**
Post-Doctoral Research Fellow

- Developed formulations of parenteral and soft gel capsules for water insoluble compounds.
- Developed micellar and liposomal formulations.
- Developed freeze-drying cycles for parenteral formulations.

ST. JOHN'S UNIVERSITY, Jamaica, NY **1985 - 1992**
Teaching Fellow (1987 - 1992)
Teaching Assistant (1985 - 1987)

- Coordinated / taught graduate product formulation laboratory and undergraduate pharmaceutics laboratory.

ESTATES PHARMACY, INC., Jamaica, NY **1988 - 1992**
Intern Pharmacist

- Filled prescriptions under guidance and supervision of Supervising Pharmacist.
- Directed and coordinated training programs for pharmacy interns.
- Managed pharmacy department including inventory control and billing third party union plans.

EDUCATION

Ph.D in Pharmaceutical Sciences; St. John's University, Jamaica, NY – May 1992
[Thesis: Iontophoretic Transdermal Drug Delivery; published in leading journals]

M.S. in Industrial Pharmacy; St. John's University, Jamaica, NY – September 1987
[Thesis: Gastric Retention System using Model Drug]

Bachelor of Pharmacy; Birla Institute of Technology, Mesra, Ranchi (India) – May 1985

PROFESSIONAL ACTIVITIES

- Licensed and Registered Pharmacist in New York State since July 1996
- Active Member of American Association of Pharmaceutical Scientists
- Served as Executive Member of American Association of Indian Pharmaceutical Scientists
- Member of Pharmacy National Honorary Society, Rho Chi
- Secretary, Pharmaceutical Society at Birla Institute of Technology, Ranchi, India: Organized seminars, debates, quizzes, exhibitions, and excursion tours.

CONTINUING EDUCATION

- FDA Drug Topics: FDA's Office of Orphan Products Development (OOPD) – An Overview and Update (April 2021)
- Understanding Depression & Bipolar Disorders (Feb 2021 by INR California; 6 hours)
- Coping with Traumatic Events: Threats, Crises, & PTSD (Feb 2021 by INR California; 6 hours)
- Understanding Diabetes: New Ideas on a Serious Epidemic (Jan 2021 by INR California; 6 hours)