# Daniel W. Frank

## Senior Regulatory Affairs Consultant

### Core Competencies

- Life Cycle Management
- Author IND/NDA
- Technical Writing
- eCTD Formatting
- Briefing Books
- Program Management
- IQ/OQ/PQ Review
- Supplier Agreements

## Professional Summary

Mr. Frank has strong knowledge of regulatory and compliance for all phases of drug development, investigational and marketing applications, post-approval changes and GMP. He brings a manufacturing and compliance perspective to his writing with his career spanning from API to finished product manufacturing.

He provides expertise in all aspects of CMC including API requirements, formulation development, scale-up, manufacturing, submission/change requirements and validation for oral, topical, and injectable dosage forms.

## Education

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| B.S. | Chemistry | Saint Joseph's University |

## Professional Experience

**Design Space Inpharmatics, LLC** **2020 - Present**

**Senior Regulatory Affairs Consultant**

- Authors CMC sections for IND/NDA/MAA and other global submissions,
- Authors briefing books and responses to agencies questions,
- Prepares annual reports, DMF and post-approval changes,
- Develops and maintains regulatory timelines,
- Labeling, advertising and promotion amendments.

**Independent Consuting** **2019 – 2020**

**Regulatory and Quality Consultant**

- Pre-IND meeting briefing package preparation; response and action plan to Agency advice for an injectable product
- INDs – strategy, authoring, submissions and maintenance
- MAA content authoring, review and strategy
- Regulatory strategy for an investigational mAb; quality advice
- FDA meeting team member and briefing package preparation,
- Post-approval variations: manufacturing, safety, and labeling,

- GMP compliance audits,
- 3D tablet printing regulatory guidance for an ODT,
- Due diligence for in-licensing development and approved products.

**Cutanea Life Sciences** **2018 - 2019**

**Manager, Regulatory Affairs**

- NDA life-cycle management,
- CMC change control strategy and regulatory review (PAS/CBE), manufacturing site, analytical test site and API supplier,
- NDA/IND annual report preparation/review,
- Regulatory representative for Ad/Promo committee,
- PSUR/DSUR input and review,
- SOP preparation and review,
- Therapeutic areas anti-infectives, acne,
- Drug products: topical.

**Aclaris Therapeutics** **2017 - 2018**

**Director, Regulatory Affairs**

- IND content authoring and review (contribute to all modules, lead CMC), preparation and submissions, including initial submissions, amendments, annual reports, and agency responses,
- NDA and EU MAA lead team member for review cycle strategy and responses,
- Labeling updates, post-approval change strategy and planning,
- Provide regulatory input, strategy, and support to cross-functional project teams (CMC, nonclinical and clinical),
- Health Authority communications, including meeting requests and briefing book preparation,
- Representative for ad/promo material review team; communication with OPDP for pre-launch advice,
- Expedited pathway program team member,
- Review/approve clinical trial documentation, investigator Brochure updates and ClinicalTrials.gov registry maintenance,
- Therapeutic areas: alopecia, vitiligo, atopic dermatitis, seborrheic keratoses and common warts,
- Drug products: topical and oral.

**NexMed (U.S.A.), Inc. (a division of Apricus Biosciences)** **1996 - 2015**

**Director, Regulatory Affairs and Quality Assurance (2005)**

- Marketing Authorization Submissions: US FDA NDA, EU MAA, Health Canada NDS and Swissmedic application,
- Strategy, content identification, preparation, submission, and health authorities review responses,
- Primary person responsible for writing NDA Quality/CMC sections; reviewed and edited preclinical and clinical sections for content and accuracy,

- Amendments, updates, annual reports, and variations,
- IND submission and maintenance including information updates, general correspondence, responses to reviewer questions and preparation of annual reports,
- Interpretation and application of FDA, ICH and EMA guidances and interaction with Health Authorities including guidance and scientific advice meetings,
- FDA guidance and milestone meetings (pre-IND, EOP2, end of review) , Ad-hoc interaction with RPMs and technical review staff,
- EU and HC scientific advice and review meetings,
- Briefing book preparation, author initial content and responses,
- Member of due diligence team for in- and out- licensing opportunities including review of Modules 1-5 with a focus on formulation and quality/compliance aspects of drug products,
- Interact with internal functional leads (e.g. CMC, clinical, nonclinical) in a matrix reporting relationship,
- Clinical and preclinical development program and study protocol review,
- Investigational Brochure writing and updates Ad/Promo and medical information development and review for regulatory compliance,
- Quality audits (GMP, GLP, GCP), Quality Agreements, Host health agency/licensee audits,
- Manufacturing documentation approval; release and OOS investigations,
- Process validation, Analytical and microbiological test results review, and approval,
- IQ/OQ/PQ review for manufacturing and analytical equipment, Stability protocols, Document control system,
- SOP authoring and CAPA system development and incident review.

**Director, Pharmaceutical Operations and Development (1996)**

- Identification and selection of API manufacturers and contract negotiation with chemical manufacturers for GMP manufacturing API DMF review and input,
- Quality audits of manufacturers and vendors, domestic and foreign,
- Identification, selection and buildout of GMP manufacturing facility for drug products, including manufacturing equipment requirements and selection,
- Interview, review bids and select architectural and engineering firms and construction contractors,
- Process development and improvement of an R&D process to commercial scale,
- Transfer of drug product manufacturing and testing to CMOs,
- Writing of technical documents for internal use and regulatory submission,
- Formulation development, including a topical solution designed for improved patient compliance compared to an existing commercial product,
- Clinical material manufacturing, packaging, and distribution.

## Wyeth Consumer Healthcare 1993 - 1996

**Senior Research Scientist**

- Responsible for the development of new OTC and Rx-to-OTC solid oral formulations as well as improvements and line extensions of existing products using conventional and improved formulation materials and processing techniques,
- Implement and manage the technical transfer of development products to commercial facilities,
- Troubleshoot and improve processes for existing products,
- Author technical documentation for regulatory submissions,

- Process validation protocol preparation and performance of IQ/OQ protocols,
- Preparation of investigation reports on out of specification (OOS) production material.

**Greenwich Pharmaceuticals Incorporated** **1988 – 1993**

**Director of Clinical Supply and Commercial Manufacturing**

- Brought a new dosage form manufacturing facility into compliance with FDA and industry standards,
- Manage equipment installation and qualifications, cleaning validations and process validation,
- Identify and prepare systems and procedures to control all phases of the manufacturing environment,
- As part of a team, perform manufacturer selection and auditing for key chemical intermediates for an API,
- Implement and manage the optimization of a manufacturing process using Design of Experiment techniques within the constraints of the regulatory filing,
- Prepared the drug product section of a new chemical entity NDA submission,
- Authored the product development report, implemented an inspection readiness plan, and led FDA field investigators through the manufacturing section during a pre- approval inspection,
- Manage all phases of clinical supply, internally and externally, for drug product manufacturing and study trial packaging.