# Nancy J. Harper, Ph.D.

## Senior Drug Product Consultant

### Core Competencies

- Parenteral
- Lyo Formulation
- Inhalation
- Oral Liquid
- FMEA Analysis
- Gap Assessment
- CMC Strategy
- Steriles
- Nebulizer

### Products

- Trovan ®
- Geodon®
- Sultamicillin ® Powder
- Selzentry ®
- Exubera ®

## Professional Summary

With over 30 years of industry experience, Dr. Harper is an accomplished pharmaceutical product development scientist with emphasis on development of parenteral, oral liquid and inhalation products. She possesses a unique talent for merging scientific rigor, regulatory expertise, and pragmatism into drug product development while ensuring that customer needs are met.

As an expert in commercial drug product design and development (formulation and manufacturing process), she applies Quality by Design (QbD) concepts, CMC regulatory strategy/authorship, technical risk assessment and problem solving. Nancy is a key contributor to clients as formulator or pharmaceutical expert in the development and successful commercialization of new drug products. She possesses experience with NCE's (human and veterinary), product enhancements, and generic products for developed and emerging markets.

## Education

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| Ph.D. | Pharmaceutics | University of Connecticut |
| B.S. | Pharmacy | Philadelphia College of Pharmacy and Sciences |

## Professional Experience

**DSI / Independent Consulting** **2012-Present**

**Senior Drug Product Consultant**

- Lyophile for injectable suspension - directed Phase 3/commercial formulation and process development activities at CMOs (active, placebo, diluent), technical problem-solving and data analysis, developed experimental strategies and study designs, CMC submission component authorship for Phase 3 IND/IMPD; risk analyses,
- Liposomal inhalation product – provided a technical gap assessment on drug product formulation and manufacturing process,
- Multiple OTC oral liquid products – led formulation and process development/scale-up; technical problem solving,
- Drug product design, development, and commercialization.

**Pfizer Global R&D, Pharmaceutical R&D** **1983 - 2011**

**Research Fellow, Life Cycle Management (2010-2011)**

- Developed a streamlined product development process incorporating QbD principles based on ICH Q8, Q9 & Q10, adaptable to the needs of fast-paced generic and product enhancement projects. As part of this process, facilitated technical risk assessments on five different projects (including parenterals, oral liquids and medical device),
- Key contributor to the EFPIA Mock Phase 2 for Small Molecule Parenteral document,
- Designed lab feasibility studies to demonstrate technical viability of several new product concepts,
- Provided strategic and technical consultation on product development and regulatory submissions for numerous generic and 505(b)(2) parenteral projects at internal and external development sites,
- Performed technical due diligence for seven parenteral and topical dosage forms product licensing and portfolio acquisition opportunities,
- Led a multi-site project team to develop product enhancements of a high-volume parenteral product (improved stability to allow room temperature storage and multi-dose option) to target launch at LOE.

**Research Fellow, Parenteral Center of Emphasis (PCoE) (2004-2010)**

- Authored (P1, P2 & P3 sections) and served as critical reviewer of all other Module 3 sections of the Exubera CTD, numerous query responses, and participated in various agency meetings as technical expert on both device and drug product,
- Created and led the Topical Product Development group (4 direct reports), including creation of a topical/ transdermal product development lab,
- Facilitated technical risk assessments on product and process design for several development projects.

**Manager/Assistant Director, Liquid Product Development (1999-2004)**

- Led two joint R&D teams in Nektar partnership on Exubera® (inhaled insulin DPI): drug product and inhaler performance and robustness characterization,
- Designed comprehensive performance characterization programs for the Exubera inhaler and drug product, including strategy definition, experimental designs, and data analysis/interpretation for the more complex and inter-related performance characterization studies. Developed scale-up strategy for spray drying and established Design Space for several CQA's for both drug product and inhaler,
- Managed the Liquids Technology Transfer group (4 senior scientists),
- Pharmaceutical Expert and Expert Report author for three European Marketing Authorisation submissions (Zoloft Oral Concentrate, Geodon IM, Advocin 180 Injection),
- Developed an IV/IVc for Exubera, enabling identification of the clinically relevant aerosol quality attributes (critical and non-critical), allowing a unique and commercially manageable approach to aerosol specifications.

**Research Scientist/Sr. Research Investigator, Liquid Product Development (1983 – 1999)**

- Formulator and Pharmaceutical Expert leading to commercialization of several liquid and parenteral products: Dectomax Pour-On, Zoloft Oral Concentrate, Geodon IM, Advocin Injection, Trovan IV.