



SAMANTHA CLACK

Independent Consultant

BSc (Hons), PGDip, CBiol, MSB

AREAS OF EXPERTISE

TRAINING

Auditing, GMP, Regulatory Update, Validation, Supply Chain and Starting Materials, Packaging, QP training modules (e.g. formulation and processing, pharmaceutical microbiology, elements of a Quality Management System)

AUDITING

Excipient, API, Finished Dosage Form and primary and secondary packaging facilities worldwide.

KEY KNOWLEDGE AREAS

Microbiologist

Solid Dose and Sterile Product Manufacture and Packaging

Quality Management Systems

Qualified Persons Training

Auditing of Excipient, API, Finished Dosage Form and primary and secondary packaging facilities worldwide.

CONTACT

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EXPERIENCE

- > Chartered Biologist since 2003. Member of the Pharmaceutical Quality Group (PQG) and performs the role of Trainee QP Coordinator, organising conferences for trainee and recently qualified QPs.
- > Extensive equipment qualification, process optimisation, cleaning, method and process validation experience.
- > Implemented key quality management systems and associated procedures as well as Batch Disposition activities for both EU and imported products including solid dose, parenteral, biotech and non-sterile liquid and gel products.
- > Extensive internal self inspection, internal audit and external supplier audit experience. Performed Third Party API, parenteral, solid dose and biotech manufacturing and packaging facilities, warehouses and marketing affiliates worldwide against both EU and US regulations for compliance with both GMP and GCP requirements
- > Delivered Corporate Quality Standards and educational packages to Company and Third Party manufacturers including a virtual auditing process and GMP training for Marketing Affiliates, both used globally
- > Experience in the manufacture and packaging of sterile ointments, gauzes and powders and non-sterile ointment, creams and liquids.

KEY JOB ROLES

- > Independent Consultant working on behalf of NSF Health Sciences performing training and auditing services
- > Multiple Contract QP roles covering aseptically filled and terminally sterilised parenteral products, sterile and non-sterile cream and ointment products, solid dose and ophthalmic products worldwide
- > Eisai Manufacturing Limited - Quality Manager Marketed Products
- > Eli Lilly & Company Ltd - Group Leader/QP, QA Operations
- > Eli Lilly & Company Ltd, - Senior Quality Associate
- Patheon UK Ltd (Formerly Hoechst Marion Roussel) - Deputy Manager, Topicals Department

EDUCATION

- > BSc Hons Microbiology
- > Eligible to act as an EU Qualified Person since May 2005

NSF HEALTH SCIENCES LIMITED

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Training www.nsf.org/info/pharma-training