

PERSONAL INFORMATION

Andrew Hopkins

WORK EXPERIENCE

March 2005–Present

Senior GMDP inspector

MHRA (United Kingdom)

Inspecting a wide range of pharmaceutical companies and blood establishments. Supporting regulatory guidance documents

September 2001–March 2005

Manufacturing Quality Assurance Manager

Patheon (United Kingdom)

Management of GMP compliance in multiple sterile filling facilities, validation and calibration activities, hosting regulatory and client audits, GMP training and cleaning validation

October 1997–September 2001

Production Manager

RPScherer (United Kingdom)

Responsible for management of day to day production activities and meeting business targets including compliance for a Softgel filling facility

October 1991–October 1997

QC Microbiologist, Validation and production Manager

Hoescht Marion Roussel (United Kingdom)

Responsible for Microbiology environmental monitoring and validation activities
Setting up the validation department . Responsible for sterile ointment, and wound dressing manufacture

EDUCATION AND TRAINING

September 1988–July 1991

BSc Honours

Cardiff University (United Kingdom)

Microbiology with Genetics

May 1995–July 1997

Post Graduate Diploma

Brighton University (United Kingdom)

Study guide for the Qualified Person role

ADDITIONAL INFORMATION

Expertise

I have multiple years experience in various aspects of pharmaceutical manufacturing with a focus on sterile manufacture

Publications

PDA Technical report No1

PHSS technical monograph for non viable monitoring.

PHSS technical monograph for Biocontamination

Projects

EDQM Water monographs expert working group

EDQM and Council of Europe good practice guide

Memberships Memeber of the Society of Biology

Other Relevant Information