

PERSONAL INFORMATION

Tracy Moore

WORK EXPERIENCE

October 2014–Present

Senior GMDP Inspector

MHRA (United Kingdom)

GMP AND GDP INSPECTION OF MANUFACTURING FACILITIES, UK and ROW

December 2011–October 2014

GMDP Inspector

MHRA (United Kingdom)

GMP AND GDP INSPECTION OF MANUFACTURING FACILITIES, UK and ROW

February 2011–November 2011

HEAD OF QA

MARTINDALE PHARMACEUTICALS (United Kingdom)

QUALITY ASSURANCE / COMPLIANCE OF UK OPERATIONS TO EU GMP & QP FOR PARENTERAL UNITS AND NON STERILE ORAL LIQUIDS

January 2010–February 2011

QUALITY SYSTEMS AND COMPLIANCE MANAGER

PATHEON INC (United Kingdom)

QUALITY ASSURANCE / COMPLIANCE OF UK OPERATIONS TO EU, US FDA, ANVISA GMP & QP FOR ASEPTIC & TERMINALLY STERILISED UNITS (ASEPTIC POWDER FILL, SOLUTION FILLED PRE FILLED SYRINGES, AMPOULES, VIALS & FREEZE DRYING OF VIALS, STERILE OINTMENTS & CREAMS) QP AUDITING OF API, STARTING MATERIALS INCLUDING PRIMARY PACK (GLASSWARE, RUBBER COMPONENTS)

January 2000–December 2009

QUALITY ASSURANCE MANAGER - STERILES FACILITY

CP PHARMACEUTICALS / WOCKHARDT UK (United Kingdom)

QUALITY ASSURANCE / COMPLIANCE OF UK STERILE OPERATIONS TO EU, US FDA, ANVISA, TAIWAN GMP & EU CERTIFICATION QP FOR ASEPTIC & TERMINALLY STERILISED UNITS (CARTRIDGES, AMPOULES, VIALS & FREEZE DRYING OF AMPOULES) QP AUDITING OF ALL SUPPLIERS

March 1999–December 1999

QUALITY ASSURANCE OFFICER

IVAX PHARMACEUTICALS (United Kingdom)

QUALITY ASSURANCE / COMPLIANCE OF SUPPLIERS FOR BLOW FILL SEAL OPERATIONS TO EU GMP

September 1998–March 1999

CONTRACT GXP AUDITOR

BRITISH BIOTECH (United Kingdom)

REPORT AUDITING TO OECD GUIDELINES

August 1996–August 1998

QUALITY ASSURANCE OFFICER

CORTEC GROUP (United Kingdom)

QUALITY ASSURANCE / COMPLIANCE OF NON STERILE DOSAGE FORM OPERATIONS TO EU GMP (TABLETS, CAPSULES, ORAL SOLUTIONS, CREAMS)

July 1989–August 1996

QUALITY CONTROL ANALYST

BRISTOL-MYERS SQUIBB LIMITED (United Kingdom)
Analysis of Non sterile and sterile dosage forms, validation activities

EDUCATION AND TRAINING

2003–May 2005 **EU QUALIFIED PERSON ELIGIBILITY**
(United Kingdom)

1993–1997 **BACHELOR OF SCIENCE - CHEMISTRY**
THE UNIVERSITY OF MANCHESTER (United Kingdom)
CHEMISTRY
CHEMICAL ENGINEERING, ANALYICAL CHEMISTRY (ALL TECHNIQUES) ,WET CHEMISTRY

ADDITIONAL INFORMATION

Expertise GMP Inspections,
Data Integrity
sterile manufacturing,
non sterile manufacturing
Eligible QP under 2001/83/EC since 2005

Publications

Projects

Memberships Royal Society of Chemistry

Other Relevant Information