

PERSONAL INFORMATION **Tracy Moore**

WORK EXPERIENCE

February 2019–Present **Expert GMDP Inspector**
MHRA (United Kingdom)
GMP AND GDP INSPECTION OF MANUFACTURING FACILITIES, UK and ROW
JAP Auditor

October 2014–February 2019 **Senior GMDP Inspector**
MHRA (United Kingdom)
GMP AND GDP INSPECTION OF MANUFACTURING FACILITIES, UK and ROW
JAP Auditor

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 COMONENTS)

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 INC APIs

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

JAP Auditor

Publications

MHRA GXP Data Integrity Guidance

Projects

Memberships

Royal Society of Chemistry

Other Relevant Information