

What technical skills* do I need as a Qualified Person (QP)?

*Please note: Technical skills set out in this guide are in addition to the requirements of the QP Study Guide



PHARMACEUTICAL QUALITY SYSTEMS (PQS)

- Able to set up systems from scratch
- Full oversight of system through KPIs/metrics
- Reporting to senior management

RELATED COURSE:

[Pharmaceutical Quality Systems](#)
[QMS Lead Auditor](#)



CHEMICAL & MICROBIOLOGICAL TESTING

- Active substance and excipients
- Packaging materials
- Finished products

RELATED COURSES:

[Introduction to Pharmaceutical Microbiology](#)
[QP Pharmaceutical Microbiology](#)
[Analysis and Testing](#)
[Active Pharmaceutical Ingredients](#)
[Water systems and microbiological control](#)



DOMESTIC & INTERNATIONAL STORAGE & DISTRIBUTION

- Effect of temperature / humidity on products
- Controls for storage and transport
- Supply chain maps
- International shipping legislation

RELATED COURSES:

[Good Distribution Practice](#)
[Responsible Person](#)
[Responsible Person Forum](#)



PROJECT MANAGEMENT

- Project planning and scheduling
- Dependencies
- Resourcing
- Reporting



RISK MANAGEMENT

- Maintenance of Risk Register
- Application of Risk Management e.g. FMEA
- Use of Risk Assessment for issue management

RELATED COURSE:

[Quality Risk Management](#)



DATA ANALYSIS & INTERPRETATION

- Performance analysis KPIs / metrics
- Statistical process control
- Analytical data calculation / understanding

RELATED COURSES:

[Introduction to Statistics for Quality Assurance](#)
[Mathematics and Statistics](#)



LEGAL FRAMEWORK

- UK and EU medicines legislation (human and veterinary)
- UK/EMA/ICH guidelines
- Product and site licensing requirements
- All other relevant guidelines

RELATED COURSE:

[Law and Administration](#)
[Roles and Professional Duties of a QP](#)



PEOPLE MANAGEMENT

- Employment law
- Resource management
- Capacity planning
- Delegation
- Performance management

RELATED COURSES:

[Leadership and Influencing Skills](#)

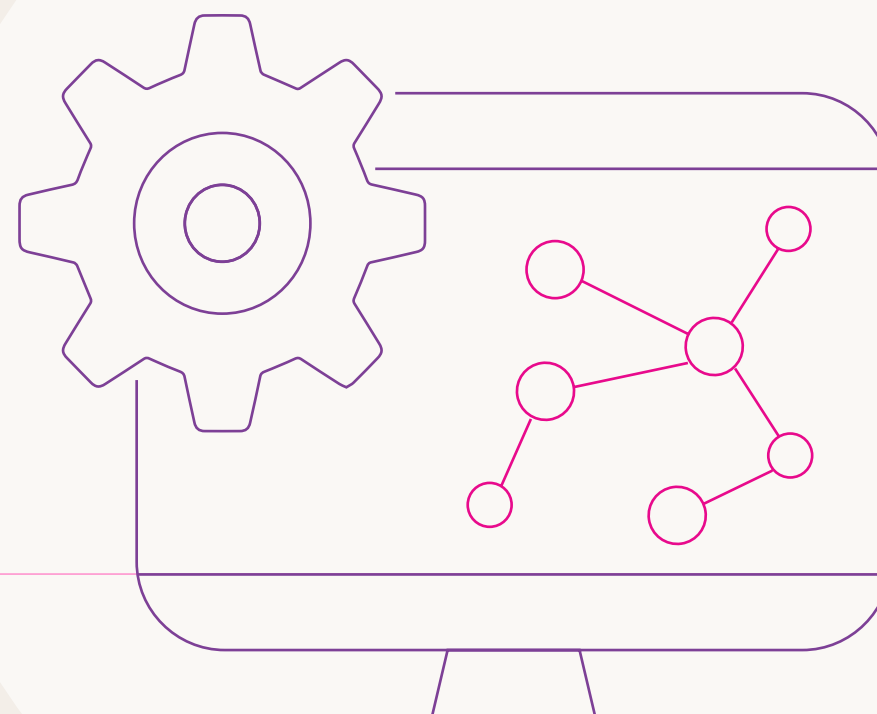


PRODUCT KNOWLEDGE

- The medicinal chemistry of products made by your company
- The disease(s) and patients being treated by these products
- Other product types (to allow extrapolation)

RELATED COURSE:

[Medicinal Chemistry and Therapeutics](#)
[Understanding ATIMP'S from bench to bedside](#)



PHARMACEUTICAL MANUFACTURING

- Manufacturing and control of your products e.g. tablets and capsules or sterile injections
- Knowledge of other product types (to allow extrapolation)

RELATED COURSES:

[Formulation and Processing Part 1](#)
[Formulation and Processing Part 2](#)
[Manufacturing Sterile Products](#)
[Good Manufacturing Practice](#)
[Active Pharmaceutical Ingredients](#)
[Pharmaceutical Packaging](#)
[Failure Investigation and CAPA](#)
[Biotechnology Issues](#)



INFORMATION TECHNOLOGY (IT)

- IT infrastructure and programmes relevant to validation and Data Integrity
- Business management application e.g. SAP, ERP
- Data capture applications e.g. LIMS, BMS
- Routine applications e.g. MS Office

RELATED COURSES:

[Data Integrity](#)
[GxP Computerised Systems Validation and Compliance](#)
[Technology Transfer of Pharmaceutical Products](#)