

# Quality assurance career path

## Key skills

- Communication
- Attention to detail
- Statistical analysis
- Problem solving
- Time management

## Key requirements

- Academic degree in medicine, life sciences, health care or related fields
- Knowledge of quality standards and production

## Employers

- Pharmaceutical companies
- Biotech companies
- Medical devices

### Protip

Experience in mentoring, training, supervising and managing other staff can help career progression.

Please note that this infographic is based on common career pathways and may not account for every direction a career in quality assurance may take you in.

### QA Specialist/Officer/Associate

Supports all quality assurance activities relating to the manufacturing, packaging, testing, storage and distribution of products.

#### Key responsibilities

- Checks the implementation of the quality management system
- Conducts quality assurance audits and records results from processes and procedures
- Responsible for logging any compliance issues

### Senior Specialist

Supports the quality assurance management team and is usually a subject matter expert in a specific area, for example, a specialist in CAPA.

#### Key responsibilities

- Reviews and approves controlled documents for Good Manufacturing Practice compliance
- Performs reviews, investigations and audits as required
- Suggests any changes to the quality processes

5-8 years of exp

### QA Auditor

Responsible for evaluating and ensuring that internal and external departments are meeting regulations.

#### Key responsibilities

- Travels to manufacturing sites and facilities to conduct audits
- Write up reports identifying areas where the supplier could make improvements
- Manage post-audit activities and follow-up on any necessary CAPA required

3+ years of exp

### Protip

Working in quality assurance can be very fast paced, therefore the ability to work well under pressure is essential.

### Professional development

Training for quality assurance roles usually takes place on the job and will vary from company to company. Some employers will offer the opportunity to take part in external training schemes, such as IRCA. By undertaking IRCA training and joining the IRCA register you will be recognised globally as an audit professional.

### QA Systems Manager

Establishes, develops and manages systems to ensure quality governance of all internal and outsourced activities.

#### Key responsibilities

- Coordinates strategic quality activities in line with the company's goals
- Provides guidance in the application of the quality management system to all stakeholders
- Develops and manages the quality management system

5-10 years of exp

### QA Operations Manager

Responsible for operations and direct line manager to the quality assurance specialists.

#### Key responsibilities

- Manages hiring, on-boarding and employee development for the QA team
- Provides quality assurance oversight, technical expertise and leadership
- Responsible for resource management and planning

5-10 years of exp

### QA Compliance Manager / QA Audit Management

Develops and drives operational quality and process improvement initiatives.

#### Key responsibilities

- Responsible for meeting regulatory bodies rules
- Develops and implements quality policies and processes
- Performs quality checks and audits and investigates any issues

5-10 years of exp

### Head of/Director of Quality

Oversees and manages all activities of quality assurance teams.

#### Key responsibilities

- Responsible for the development and execution of quality assurance processes and ensures compliance with the established standards
- Manages corrective action as well as preventative actions to the quality process
- Approves analytical reports, any changes in processes, and any recommendations

10+ years of exp

### Head of Compliance/Auditing

Oversees and has overall responsibility for the company's compliance program and quality assurance department.

#### Key responsibilities

- Oversees the implementation of the compliance program
- Provides strategic direction to the management team on compliance
- Presents clear and concise compliance reports to the wider company

10+ years of exp

### QP (Qualified person)

Ensures that every batch released to the market legally complies with its specification and has been made in line with Good Manufacturing Practice guidelines.

#### Key responsibilities

- Interact with relevant regulatory bodies
- Perform and participate in internal/external audits
- To review and evaluate batch records and authorise batch disposition

The road to becoming a QP varies from country to country but usually involves a rigorous training process that can take several years. As QPs are responsible for certifying batches, they must have expertise in not just manufacturing but they must also understand the factors that can affect the safety of medicines and supply chains. They are often involved in audits and will be the go-to person for technical advice and if there are any issues.

### VP of Quality

Responsible for the strategic development and execution of the quality assurance department.

#### Key responsibilities

- Provides leadership and mentorship to the quality assurance team
- Ensures quality metrics comply with best industry standards and practice
- Maintains effective quality governance to meet business and compliance needs

20+ years of exp

### Protip

When working in quality assurance you must be able to quickly identify problems and suggest pragmatic and practical solutions