



# RSSL Auditor Career Pathway

For Life Science professionals

Foundation Level (0-2 years)

# Foundation Level

0-2 years in pharmaceutical manufacturing, quality assurance or research and development.

## Where do I start?

At this stage of your career, you are more than likely still learning pharmaceutical Good Manufacturing Practices (GMP) and applying them to your role. You may be receiving audits and might be curious about conducting audits yourself, or perhaps it's part of your development plan.

**As you plan how you wish to progress in your role, collaborating with your manager to set targets and goals is essential. Some development considerations could include:**

- **Taking ownership and learning on the job:** your personal development plan should focus on hands-on learning. Applying your knowledge in real-world scenarios is the best way to grow (see the auditing skills to the right).
- **Training interventions:** consider auditing training sessions to kick-start your journey (see the mapped RSSL courses to the right).
- **Coaching and mentoring:** ideally, seek out a coach or mentor who can guide you and help you improve.

## FOUNDATION (0-2 YRS)

- QA Associate / Officer
- Internal Auditor
- Trainee Auditor / Auditor



- Basic knowledge of statutory regulations and guidelines
- Conduct and plan non-complex self inspection internal audits
- Identify references when reporting non-conformances
- Write clear audit findings
- Internal audit report writing
- Professional communication skills



- Auditing to pharmaceutical standards
- GMP Introduction
- PQS-Audits and self-inspection eLearning
- Internal Auditor





What's important to know and be capable of doing at this stage of your career?



# Understanding GMP standards and guidelines

These GMP standards and guidelines are essential to learn and form a foundation for your auditing career.

**You should familiarise yourself with:**

- **EudraLex GMP Volume 4 – GMP Part 1 (Chapters 1-9).** These are the core basic GMPs that you need to know and be able to apply in an everyday working environment. In particular, you should memorise the chapter headings so that you can recall them quickly during an audit.
- **EU GMP Part II** covers Active Pharmaceutical Ingredients; you may need to know it at a basic level, for example if you're working in a lab and testing materials. It could be that you are working with suppliers, so a good understanding of APIs might be of use so you can understand the requirements a bit better.
- **EU GMP Part III** covers specialist documents that give a narrative on particular segments of the GMP lifecycle. Important to an auditor is ICHQ10, plus the specific Annexes – especially Annex 15 validation, Annex 1 if your company makes sterile products, etc. The key advice is to know that they exist and read the ones relevant to the products you make.
- **Other industry guidelines** are available for excipients, packaging materials, data integrity, Good Distribution Practice, among others.
- **Worldwide international guidelines** – you may be working for a company that supplies outside UK/Europe, such as USA CFRs, PIC/S, WHO.



**Recommended:**  
**Auditing to Pharmaceutical Standards**



**Good Manufacturing Practice - the essentials**

**Good Distribution Practice**

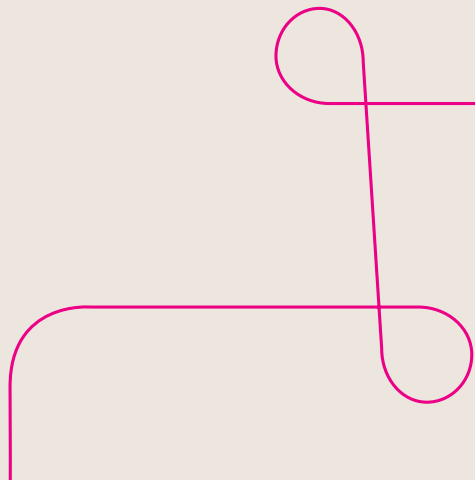
During each of the above one day courses, we take a deeper look into the guidelines to help you understand how they apply in an auditing context.



# Understanding the auditing lifecycle

The most common story we hear about those on their auditing career journey is that they started without any guidance or knowledge of the auditing lifecycle. They joined as a co-auditor, or received audits and inspections and then they just had to learn on the job!

Auditing when you know the auditee is likely to have more knowledge than you can be a stressful task, especially if your approach is unstructured.



# Attend an audit training course

Our two-day Internal Auditor course is the perfect choice at this stage of your career, taking you through each stage of the ISO auditing lifecycle.



There is a dichotomy during your early years in auditing - the only way to learn is to audit, but that can be scary as it exposes your inexperience!

At RSSL, all our courses use practical learning techniques – you really do conduct audits on our course, all done in a positive and safe learning environment.

Our tutors guide you and share their experiences and tips to help you start your competence development in auditing!

## Get auditing and apply your learning!

Now that you have the framework, its time to put it into practice:

- 1. Plan and conduct audits:** start planning and conducting your audits. Don't be afraid to take the lead. Seek a designated coach or mentor (such as a Lead Auditor) to guide you along the way.
- 2. Study excellence:** observe excellent auditors whom you respect and admire. Pay attention to their behaviours:
  - a. How do they structure their audit plans?
  - b. What techniques do they use during meetings to engage with the auditee?
  - c. How do they ask questions during interviews?





# Continuing Professional Development

CDP? I've only just started my auditing journey...

Everyone, no matter whether you're on day one or year five of your career, has a role and a job description. There will be gaps in your knowledge and skills.

CPD helps you to observe, listen and learn from experts and peers in a structured way. If you want to get serious about auditing, your journey and personal auditing development plan starts today!

- Apply training theories in real life situations, actively seek feedback for ongoing improvement
- Learning from industry thought leaders, articles and events
- Keep up to date with the latest auditing methods, and regulatory environment auditing trends
- Gain specialist knowledge related to your work
- Continue your learning by attending advanced training as you reach learning milestones
- Meet IRCA CPD requirements where certified (e.g. number of audits per year, continued training).

## Join the RSSL auditing CPD community:

- Attend our regular live webinars
- Listen to podcasts for expert insights and auditor experience
- Explore our knowledge hub for articles, regulatory updates and resources
- Participate in discussions on specific auditing topics
- Access specialist auditor training modules
- Utilise our alumni network to grow your network and continue your learning.



# About RSSL Training & Consultancy

We've been training and developing pharmaceutical, biopharmaceutical, medical device, and healthcare professionals across the complete lifecycle of pharmaceutical products for over 30 years. We know what it takes to succeed and employ leading industry experts to deliver the most up-to-date training and CPD so individuals can achieve their career aspirations and companies have the skills they need to excel on the global stage.



## **RSSL Training & Consultancy**

The Reading Science Centre,  
Whiteknights Campus,  
Pepper Lane,  
Reading,  
Berkshire RG6 6LA

Tel: **+44 (0)118 918 4076**

Email: **[trainingsales@rssl.com](mailto:trainingsales@rssl.com)**

Web: **[www.rssl.com](http://www.rssl.com)**

© 2024 RSSL. All rights reserved.

