IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Best Practices for Supplier Qualification in Life Science

26-27 May 27
+ 11-12 November 27

Explore the intricacies of Life Science Supplier Qualification through our comprehensive course. Gain expert insights into regulatory compliance, supply chain optimization, and strategic sourcing. Elevate your proficiency in maintaining product integrity with proven industry best practices.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Conduct thorough supplier qualifications and audits to strengthen the quality systems of your pharmaceutical, biotechnology, and medical device manufacturing processes.

Ensuring suppliers consistently meet quality requirements is paramount across all materials and services procured. Regulatory agencies such as FDA, EMA, MHRA, TGA, PIC/S, and ISO 13485 have intensified their focus on supplier qualification. The 2015 update of the EU GMP Guide notably emphasised supplier selection and qualification in Chapter 5, marking a significant regulatory shift.

While supplier qualification may have been unfamiliar decades ago, it has now become integral to industry practices. Qualifying suppliers, especially those in regions like China and India, presents unique challenges, demanding additional responsibilities for both parties. Beyond audits, establishing effective "Quality Agreements" is essential. Prior to outsourcing, companies must define minimum product specification and user requirements to ensure compliance with GMP standards. Each product may necessitate specific evaluation criteria during initial technical visits to potential supplier, involving assessment of SOPs, Quality Management Systems, previous audits, organisational structure, and task distribution.

This course equips participants with practical strategies to navigate complex supplier qualification processes, enhancing compliance, and optimizing quality management systems to meet stringent regulatory expectations. Delegates will gain comprehensive strategies and insights into conducting rigorous supplier qualification and audits to enhance the quality systems across pharmaceutical, biotechnology, and medical device manufacturing processes.

Bonus documents included:

- Supplier qualification questionaries (API, excipient, packaging material)
- Supplier evaluation matrix
- Risk-based supplier audits
- Quality Agreement
- Supplier qualification sample SOP
- FDA inspection findings, example warning letters, Form 483s
- Warehouse, logistics service provider qualification documents

Benefits of attending

- **Learn** supplier source search criteria
- **Understand** key considerations in supplier selection
- **Develop** skills in preparing supplier pre-evaluation questionnaires
- **Discuss** strategies to overcome constraints in supplier audits
- **Formulate** effective performance evaluations for suppliers
- **Gain** insights into evaluating suppliers from different perspectives
- **Witness** exemplary practices in pharmaceutical and medical device industries, exceeding health authority and GMP expectations.

Who should attend?

Professionals working in pharmaceuticals, biotechnology or medical devices, including:

- Quality Assurance/Quality Control Specialists
- GMP Compliance Officers
- Validation Professionals
- Engineering Personnel
- Operation Staff
- Manufacturing Professionals
- Supply Chain
- Logistics Staff
- IT Personnel
- Purchasing Managers

Programme

Day 1

Supplier Qualification Introduction

- What is supplier qualification?
  - Why should qualification be done, who requires/expects It?
- International guidelines and directives for supplier qualification
  - Overview of legislation, health authority expectations
  - International Trade Laws
- Is the ISO 9001 certificate only sufficient for supplier qualification?
- Why should the purchasing unit receive GMP training?
  - What should be the scope of training?

Quality Management System and supplier qualification

- What is change control?
- How should deviations be managed?
- How are complaints, recalls, and supplier qualification related?
- What is the role and importance of purchasing in supplier qualification?
- Can quality assurance, supplier, and purchasing cooperation be achieved?

Sampling and test reduction

- What does reduced testing mean?
  - What are the health authority expectations for reduced testing?
  - What should be done before test reduction?

Raw materials and service providers

- Should active pharmaceutical ingredients (APIs) and excipients be evaluated using the same method?
- How to qualify service providers?

Medical device suppliers

- Medical device supplier qualification process (21 CFR Part 820, MDR, GHTF, ISO 9001, ISO 1497, ISO 13485)
  - PIP breast implant scandal

Flow of supplier qualification & documentation

- How does the relationship between audits and supplier qualification begin?
- Who performs qualification activities?
- How do we know who does what – Manufacturer or Distributor?
- How will we document our supplier qualification activities?
- What is the qualification cycle?

Group exercise: Review of an existing supplier categorisation and evaluation study

- Critique of format
- Critique of content

Workshop: Supplier categorisation & evaluation

- Breakout groups to review and suggest improvement in the selection of supplier categorisation and evaluations.

Day 2

Supplier auditing

- Why are audits necessary and critical?
  - Risk-based audit planning.
  - To audit or not to audit?
  - What should the frequency of supplier audits be?
  - Different approaches to different suppliers

Quality agreement preparation

- What are Quality Agreements and why are they needed?
  - What should and should not be included in quality agreements?
  - Tips for negotiating an agreement.
  - How to troubleshoot common deficiencies?
  - Who prepares and approves the quality agreement? / Roles - What are the responsibilities?

Supply chain risk management

- How should unexpected incidents be managed?
- How to apply risk management in supply chain? Cases
- What to consider when purchasing from Asian countries?
  - How to overcome cultural difference problems in purchasing from India and China?
  - How should we audit in India and China?
  - What are the most common quality deficiencies?
  - What is the latest situation of the pharmaceutical market in India and China? (Legal Requirements, Authority Approaches)
  - What are the GMP violations in China and India?
  - What about audits in Europe and Latin America?
- Which documents are enough to make a company legal / illegal?
- Supply chain risk mitigation strategies.
- Supplier qualification and digital technologies

Group exercise: Review of an existing supplier Quality Agreement

- Critique of format
- Critique of content

Workshop: Supplier Quality Agreement

- Breakout groups to review and suggest improvement in supplier quality agreement.

Presenter



Mustafa Edik

Mustafa Edik is a leading pharmaceutical, biotechnoloy, medical device quality and GXP expert with over 28 years of hands-on leadership in GMP, GDP, GCP, GLP, and broader GxP compliance across the pharmaceutical, biotechnology, and medical device industries.

As Turkey's first IRCA-certificated Lead Auditor for GMP and Pharmaceutical Quality Management Systems (PQMS), he brings unmatched credibility and depth to audits, compliance strategies, and regulatory readiness. Holding a BSc in Chemistry, and a BSc (Hons) in Biopharmaceutical Sciences & Engineering from Atlantic Technological University (Ireland), and an Executive MBA, Mustafa combines strong scientific foundations with strategic business acumen.

His career highlights include senior roles at Bayer Türkiye, where he progressed from Quality Control Lab Supervisor to Deputy QA Manager, and GMP Lead Auditor to Global GMP Lead Auditor, managing complex quality operations and audits in a multinational environment. He has personally led more than 4,200 hours of GxP audits across over 200 facilities worldwide.

Today, as Founder and Lead Consultant at Quality Academia Eğitim & Danışmanlık, Mustafa delivers high-impact consulting, training, and project management services to local and global clients. His expertise spans across:

- GMP/GDP audits and supplier qualification
- Validation, qualification, and quality risk management (ICH Q9)
- Root cause analysis, CAPA, OOS/OOT, change control, and data integrity
- Sterile/non-sterile manufacturing, process improvement, and cost-of-quality optimisation
- Clinical trials (GCP & ICH E6), pharmacovigilance, and third-party manufacturing
- Regulatory alignment with FDA, EMA, PIC/S, MHRA, TGA, TMMDA, WHO, and ICH standards

Mustafa has trained over 9,000 professionals in GxP topics and designed certified auditor programs for Turkish authorities including Turkish MOH and Ministry of Agriculture and Foresty. He served as Principal GMP Consultant & Auditor at the Turkish Atomic Energy Authority, supporting successful TMMDA GMP approvals for 5 radiopharmaceutical products. As the first Turkish consultant selected by the Developing Countries Vaccine Manufacturers Network (DCVMN), he has led teams of 100+ engineers, auditors, and quality specialists while managing dozens of international projects.

A prolific author, Mustafa's works include:

- “Sorularla GMP Dokümantasyonu” – a practical guide to GMP documentation
- “GMP Audits in Pharmaceutical and Biotechnology Industries” (Taylor & Francis / CRC Press, June 2024) – a comprehensive reference on effective GMP auditing practices

Recognised internationally for his practical, risk-based approach and knowledge transfer focus, Mustafa Edik is dedicated to elevating pharmaceutical quality standards, helping companies achieve compliance excellence, reduce risks, and drive operational efficiency.

Course dates

26-27 May 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17136*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 31 Mar**
11-12 November 27	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 17479*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 16 Sep**

How to book

Online:
ipi.academy/2837

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

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+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

Since my experience in Quality Agreements is low, [I hoped to] learn more about Supplier Risk Assessments, Supplier Qualification system and [especially] relevant Regulations. [I found] Content--> more than adequate. Presentation--> interactive and effective. Speaker--> accurate, helpful.

Ifigeneia Panagou
Quality Assurance Officer
Lavipharm SA
Mar 27 2025

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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