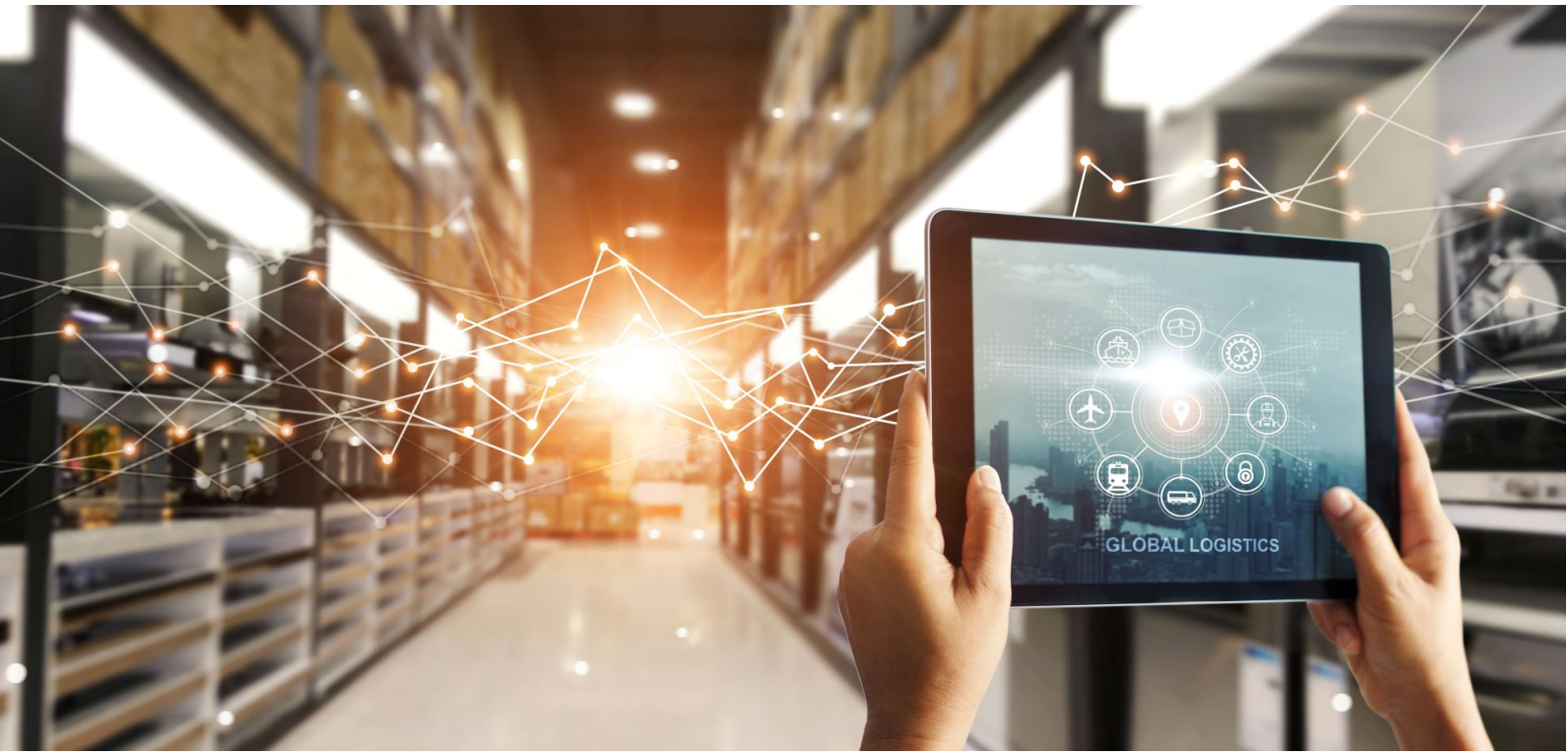
IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Best Practices for Supplier Qualification in Life Science

15-16 July 2024
+ 27-28 November 2024, 27-28 March 2025

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

Overview

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

Regardless of the material or service procured, ensuring suppliers consistently meet quality requirements is paramount. Regulatory agencies like FDA, EMA, MHRA, TGA, PIC/S, and ISO 13485 have intensified focus on supplier qualification. Notably, the 2015 update of the EU GMP Guide emphasized supplier selection and qualification in Chapter 5. This marked the first mention of "QUALIFICATION" in the GMP Guide. The revised chapter delineates separate requirements for APIs and Excipients.

While the concept of qualifying suppliers may have been unfamiliar decades ago, it is now integral to industry practices. Qualifying suppliers, particularly those in China and India, presents significant challenges, necessitating additional responsibilities for both parties. However, supplier qualification extends beyond audits; successful "Quality Agreements" are crucial. Before outsourcing, companies must define minimum product specifications and user requirements, ensuring compliance with GMP. Each product may have specific requirements, necessitating thorough evaluation during initial technical visits to potential suppliers. Assessing SOPs, Quality Management Systems, previous audits, organizational structure, and task distribution aids in preliminary evaluation.

Bonus Documents

- Supplier Qualification Questionnaries (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

- 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 an Independent GMP Consultant and Auditor.

After graduating as a Chemist from university, Mustafa began his 25 year plus career as a Laboratory Supervisor at Bayer, a German Pharmaceutical Company. After 15 years of working as a Quality Assurance Assistant Manager, Laboratory Supervisor, Pharmaceutical Quality Management Systems, and GMP Lead Auditor, he decided to continue his career as a Consultant. He has served the Turkish Atomic Energy Authority (TAEA) as Principal GMP Auditor and Consultant for 6 years. TAEA was audited by the Republic of Turkey Ministry of Health and granted GMP Certificate for 5 Radiopharmaceuticals. This success has won great acclaim from all health authorities and industry.

He has prepared and presented various training courses and workshops to more than 8000 individuals from 150 International and local Pharmaceutical, Medical Device, and Cosmetics companies on GMP, GDP and Pharmaceutical Quality Management Systems. He has taken part in several International Pharmaceutical Facility Establishment projects as GMP Consultant and has also set up various Quality Management Systems for Local Pharmaceutical and Medical Device Companies.

While he was the Vice President of Quality and Technical Operations at a Quality Academia Training and Consultancy firm, he acquired and converted it into a 100 % Turkish Company. As the only IRCA Certificated Pharmaceutical Quality Management Systems and GMP Lead Auditor in Turkey, he currently conducts API, Excipient, Packaging Materials Suppliers and Manufacturers, Third Party Logistics Service Providers, Sterile and Non-Sterile Manufacturing Facilities Audits according to FDA, EMA, PIC /S, TMMDA, MHRA, TGA Health Canada, and WHO regulations and guidelines.

He finished his second university degree in Biopharmaceutical Sciences BSc (Hons) at Atlantic Technological University - Ireland. He is the author of chapter 6 of the book published by PDA named “Good Distribution Practices” and he is preparing his latest book on ‘GMP Audits’ which will be published by Taylor & Francis in 2023.

Course dates

15-16 July 2024	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 15174*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 10 Jun**
27-28 November 2024	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 15175*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 23 Oct**
27-28 March 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 15176*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 20 Feb**

How to book

Online:
ipi.academy/2837

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

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% 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

Run this programme in-house for your whole team

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ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipi.academy