



**Qualitas
International
Certification Ltd. UK**



**Qualitas Certification
FDA - WHO - GMP - GLP - GCP - Part 11
Validation - Remedation Services**

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Qualitas Certification FDA - WHO - GMP - GLP - GCP - Part 11 Validation - Remediation Services

Our Vision:

We aspire in association with our international alliances to become a premier key services & solutions provider to a wide range of industries in the region.

Our mission is to promptly provide our customers with superior quality and cost effective services and products, while maximizing the welfare of our stakeholders.

Our Mission:

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General Objectives:

To become a recognized supplier for the Quality testing , inspection and Standard Certification industry.To support businesses with the latest Know How in the field of Environment Management System MIS Auditing .To expand our scope of supplies in the FDA/GMP & CE Marking sector.To continuously pursue profitable growth opportunities to our clients business throw QMS Auditing and certification .To provide the means to assist our customers in achieving their goals.To develop joint ventures with regional and international Training , Auditing and Certification industry leaders.To provide a rewarding and pleasant working environment for our international accreted auditors and team .



QUALITAS INTER NATIONAL GMP/ GXP COOPERATION

In order to achieve its mission Qualitas International Certification Ltd. UK is in regular contact with national- and intergovernmental bodies, such as:

- European Commission (EC)
- European Medicines Agency (EMA)
- European Directorate for the Quality of Medicines (EDQM)
- European Parliament (EP)
- US Food and Drug Administration (FDA)
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- World Health Organization (WHO)
- Council of Europe (CoE)
- Pharmaceutical Inspection Cooperation Scheme (PIC/S)

In addition, QUALITAS INTERNATIONAL CERTIFICATION LTD. UK seeks to coordinate with other related industry associations, such as:

- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- European Generic medicines Association (EGA)
- International Pharmaceutical Excipients Council (IPEC)
- International Federation for Animal Health (IFAH)
- US Generic Pharmaceutical Association (GPhA)
- European Association of General Public Specialties (AESGP)
- US Synthetic Organic Chemical Manufacturers Association (SOCMA)

QUALITAS INTERNATIONAL CERTIFICATION LTD. UK participates in and contributes to conferences, round tables and workshops dedicated to APIs and intermediates in order to monitor developments and present our views, Since 2011, we has been organising the annual "QUALITAS INTERNATIONAL CERTIFICATION LTD. UK European Conference on GMP Pharmaceutical Ingredients", which has developed into the number one conference in Europe on GMP- and RA aspects of APIs and intermediates

Qualitas International Certification Ltd. UK is an active member of:



**American Association of
Pharmaceutical Scientists**



GMP•GLP•GCP•ICH•ISO•Part 11



Our Professional Services

Qualitas has the resources and experience to assist your organization to remediate its quality and compliance gaps so that you can achieve your quality goals more quickly and efficiently.

Often an unplanned part of achieving compliance goals, mitigating or eliminating audit and assessment findings can take time and resources beyond what was originally intended. Our proven ability to design and implement scalable, cost-conscious and creative solutions uniquely qualify us to resolve audit findings quickly and efficiently.

Auditing Services:

- GMP, GCP, GLP, QS and Part 11 / Systems Audits .
- 21 CFR Part(s) 11, 210/211, 820, ICH Q7 .
- Food and Supplement GMP Audits .
- Mock FDA - EMEA Audits .
- Pre-Site Inspections - 'For-Cause' .
- Quality Assurance Audits .
- Quality System Audits - Part 820 .
- SOPs, Quality Assurance and Standards Audits .
- GMP - Good Manufacturing Practice Audit .
- GCP - Clinical Audits - Regulatory Audits .
- Equipment Validation Documentation Audit .
- Software / Systems Validation Audits .
- Part 11 / Annex 11 Compliance .
- Vendor & Supplier Audits .
- CMOs, Laboratories, API Manufacturers .
- CROs, Investigators, Monitors, and Study Sites .
- Database Audits, SAS, CMMS, eDC, eCFR, Safety .

Remediation Services:

- Project Management and Support Services .
- Gantt and Timeline Development .
- Validation Development and Executions .
- Training Services .
- Template Implementation .
- Procedures and Practice Challenges .
- Standard Operating Procedures Development .
- Development Part 11 Initiatives .
- Design / Build Engineering Services .
- Certified AIA 'As-Built' Drafting Services .
- Process and Equipment Validation Services .
- Software and Systems Validation Services .
- Design / Build Engineering Services .





Qualitas Profesional GMP/ GLP Certified Expert Programs

The QUALITAS INTERNATIONAL CERTIFICATION LTD. UK "QIC,UK"

Our Auditor Certification – how does it work?

If you aim to obtain the "QIC,UK" Auditor Certification you have to complete one of the Compliance Courses and the Auditor Training Course!

Prerequisites to become an "QIC,UK" Certified ICH Q7 Auditor

In order to become an QUALITAS INTERNATIONAL CERTIFICATION LTD. UK Certified auditor the following prerequisites have to be fulfilled:

- You should have at least ONE years practical experience of GMP compliant manufacture in the pharmaceutical industry or API industry
- You should already have conducted at least 3 external audits in the last 3 years. At least 1 audit per year should have been related to APIs, Intermediates or Starting Materials with ICH Q7 as standard
- You have to complete one of the Compliance Courses before you take part in the Auditor Training Course.
- You have to pass a written exam directly after the Auditor Training Course
- You also have to pass an Internet-based exam appr. two weeks after the Auditor Training Course

The QUALITAS INTERNATIONAL CERTIFICATION LTD. UK Auditor Certification – when does it expire and how to re-certify?

The auditor's certification is valid for 3 years.

The certification can be extended for another 3 years provided

- you have attended at least two training course/conference on current GMP topics during the current period of certification and
- you have satisfactorily performed at least three audits during the current period of certification and
- you have taken another internet-based test at the time of your next re-certification.

The API Compliance Institute keeps a register of all QUALITAS INTERNATIONAL CERTIFICATION LTD. UK Certified auditors.





GMP International Master Reference Guide

In cooperation with GMP Publication USA , Qualitas International Certification Ltd. UK offer your company the most important 900 pages of GMP guidances and regulations to ensure your compliance is up to date! Includes US, EU, ICH, Canadian and Japanese!

Just contact us on:

info@qualitascert.co.uk

Includes:

US FDA Title 21 CFR Parts

- Part 11 Electronic Records; Electronic Signatures with scope & Application
- Part 11 - Auditor's Check List
- Part 58 - Good Laboratory Practice
- Part 111 - Dietary Supplements GMPs
- Parts 210/211 Drug GMPs
- Parts 210/211 Drug GMPs - Auditor's Check List
- Part 820 Quality Systems Regulations
- Part 820 QSR - Auditor's Check List
- ICH Q7 Active Pharmaceutical Ingredients (APIs)
- ICH Q7 - Auditor's Check List
- ICH Q8 - Pharmaceutical Development
- ICH Q9 - Quality Risk Management
- ICH Q10 - Pharmaceutical Quality System
- EU GMPs Chapter 1 – 9
- Canadian GMPs 2009 Edition GUI-0001
- Japanese GMPs



GMP Publications, Inc., Online Book Store

U.S. Food & Drug Administration (FDA)

U.S. FDA Code of Federal Regulations & EU, ICH Mini Handbooks

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Our Accreditations

We have been assessed against internationally recognized standards and operate to the highest levels of quality and service.

We are accredited by local and international bodies, below some of them .

UK Register of Learning Providers
Reference Number (UKPRN) 10048767.



british standards institution bsi
Associate Consultant Programme (ACP)



(GTACS)



The UN Global Compact



The National Council for Work Experience



National Association of Student Employment Services





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