QUALIFIED PERSON SERVICES

CAI is instrumental in creating and implementing a Pharmaceutical Quality System (PQS) that encompasses all elements for delivering safe and effective products to patients: production, laboratories, materials management, facilities and equipment, packaging and labelling, and quality systems. The **Qualified Person** (QP) is a unique role in European legislation within the pharmaceutical industry. By the very nature of the job, an experienced QP develops the skills to be considered a Subject Matter Expert in multiple aspects of operations. What is of equal importance to this acquired knowledge is the application. On an everyday basis, the QP applies this knowledge in a pragmatic, risk-based, and scientific manner, with patient safety at the forefront of their consideration.

CAI actively recruits experienced QPs to provide their unique skillset to clients and be included on Manufacturing and Importation Licences. Having a QP available to clients on-site provides flexibility to respond to manufacturing and personnel changes. These QPs will become agents of change for the industry based on Quality Risk Management principles in ICHQ9, ICHQ10, and ICHQ11.

While our QPs can capably deliver the full range of Quality, Compliance and Regulatory consultancy services, we also offer niche services best filled by a QP.

QP SERVICES:

- Perform activities as per Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Annex 13: Manufacture of Investigational Medicinal Products, and Annex 16: Certification by a Qualified Person and Batch Release
- GMP auditing, QP declarations, Health Authority dossier review, supply chain map preparation, implementing Quality Risk Management (QRM), and Product Quality Review (PQR) activities

BASIS FOR QP DECLARATION OF GMP EQUIVALENCE:

- Perform a GMP equivalency audit, developing and helping to implement a remediation program
- Providing full quality oversight during batch manufacturing of the API/drug substance (DS) or drug product (DP)
- Completing required batch record and testing review as part of the batch disposition process as set out in the provisions of Annex 13 for importation of Investigative Medicinal Product (IMP) from a 3rd party country and Annex 21 for Importation of medicinal products

QUALIFIED PERSON SERVICES

GOOD DISTRIBUTION PRACTICE:

- Our QPs have an in-depth knowledge of the requirements of the EU Guideline on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01) which ensures we can provide our clients with advice and guidance for the most suitable supply chain and distribution model
- Members of our team can act as the Responsible Person (RP) on behalf of our clients

MANAGING QUALITY ASPECTS OF A CONTRACT MANUFACTURING ORGANISATION (CMO):

- Our QPs can fulfill multiple roles from initial CMO evaluation and selection
- Quality Agreement generation and approval
- Ongoing documentation review
- Placing an experienced QP on the manufacturing floor at the CMO
- Providing quality oversight during the manufacture of your product

MENTORING OF INEXPERIENCED QPs:

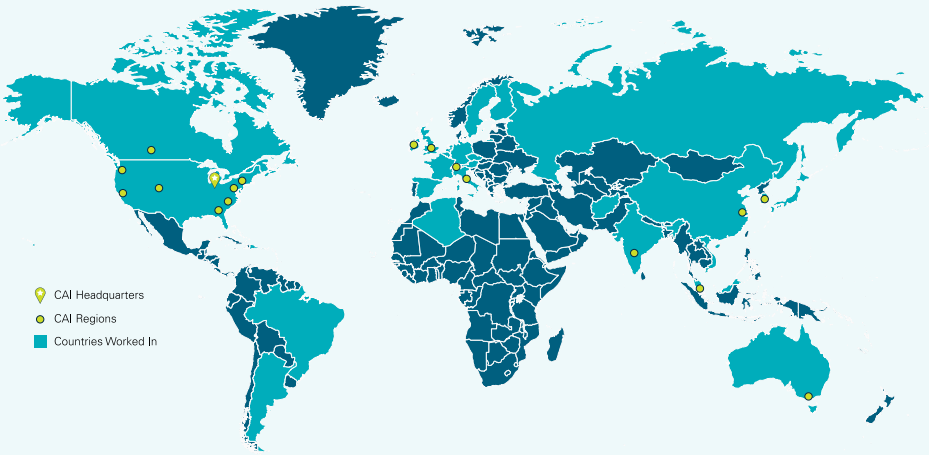
- Our experts are leaders in the mentoring of inexperienced QPs by supporting them through compliant batch disposition and providing compliance advice and guidance on product and batch-specific issues supporting the client QP make the right compliance related decisions
- This service can be transitioned from on-site to a remote service as needed

CAI AT-A-GLANCE

We exist to be the trusted solution for our clients as they strive to build a better working world and improve the human experience.

- Founded in **1996**
- **800+** Global Resources
- **100%** Employee-Owned
- **20** Regions Worldwide
- **8** Service Areas of Expertise
- Have supported **85%** of the top 20 Life Science companies*

*Ranked by 2020 revenue



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