ThermoFisher SCIENTIFIC

QUALIFIED PERSON (QP) SERVICES

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QUALITY & INTEGRITY

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Qualified person (QP) services

When carrying out clinical trials within the European Union (EU) using Investigational Medicinal Products (IMPs) that have been manufactured and/or tested outside the EU, there is a requirement for a Qualified Person (QP) to sign a 'QP Declaration' stating that IMPs have been manufactured according to standards of Good Manufacturing Practice (GMP) at least equivalent to those applied in the EU.

This is a specific requirement of EU directive 2001/20/EC and as such, applies to all EU member states and other states within the European Economic Area (EEA).

There is a regulatory expectation within the EU that QP Declarations are supported by evidence, normally in the form of an audit.

Our clinical trial solutions include comprehensive services for the preparation of QP Declarations and performing supporting audits that may be required.

To help you prepare for your regulatory submissions within the EU, we encourage you to discuss potential requirements with one of our QPs at the earliest opportunity. If audits of manufacturing facilities are required to support the QP Declarations, these must be scheduled as soon as possible to avoid delays in the regulatory approval process.

Our team of QPs bring extensive experience across a wide range of dosage forms including aerosols, biologicals, creams, liquids, ointments, solids, sterile products and novel drug delivery systems.

Our QPs are trained as ISO Lead Auditors and have extensive experience in auditing facilities across the world.

Services include

- Acting as auditors to provide documentary evidence to support the QP Declaration
- Providing advice to the Sponsor at any point during the clinical trial supply chain on issues including expiry updating
- Meeting the requirements of any conditions applied by the authorities to a clinical trial approval
- Certification of individual batches of clinical trial materials for use at any sites within a state, following authorization by the EU member state for the clinical trial to proceed
- Providing advice on documentation required to support individual batch release prior to distribution within the EU
- Providing QP Release Certificates for individual batches as well as re-issuance of QP Release Certificates during trial as further countries are approved by regulatory authorities
- Advice on named patient studies and compassion-ate use programs
- Full UK services including new QP oversight needed to comply with new EU/UK law

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