



- **Licensed QP Release**
- **Auditing Services**
- **Importation/Warehousing**
- **Quality Management System Development**

## OUR BUSINESS

# CILATUS

## MANUFACTURING SERVICES

- **Cilatus Manufacturing Services' core business is to provide End-to-End QA review and QP release services for commercial and investigational medicinal products.**

---
- **We can fully support our clients by providing a comprehensive range of QA services** including Quality Management System Design, completing Supply Chain Maps, QP Declarations, Dossier Review and Product Quality Review activities.

---
- **We are licensed by the Irish Regulatory Authority (Health Products Regulatory Authority) to QP certify batches.**

---
- **Our Quality Assurance Team has in-depth knowledge of biotechnology and traditional pharmaceutical manufacturing processes.**

---
- **As per the Good Distribution Practice Guidelines, our team experts can act as Responsible Person(s) on behalf of our clients if required.**

---
- **The team's detailed knowledge of Good Distribution Practice requirements (EU Guideline 2013/C 343/01) ensures we can provide our clients with advice and guidance in relation to the most appropriate supply chain and distribution model. We can add a client's products to our licences, leading to efficiency and cost benefits.**

---



## Licensed QP Importation into the EU and Exportation from the EU through Dublin, Ireland

- **EU GMP regulations require that Drug Product manufactured outside the EU must be imported to a site which has the appropriate licence.** The Cilatus Manufacturing Services licence enables us, if the client desires, to qualify, elect and contract with a logistics and warehousing company to facilitate importation of drug product into the European Union.

---

- **Our team has experience of performing auditing in multiple countries globally** and have detailed knowledge of global regulatory authority requirements (FDA, EU, Japan).

---



#### **HEADQUARTERS**

Cilatus Manufacturing Services Ltd.  
2 Harbour Square, Dún Laoghaire  
Co. Dublin, Ireland  
Phone: +353 1 908 1211

[www.cilatusmanufacturingservices.com](http://www.cilatusmanufacturingservices.com)

#### **CONTACT**



Daire Begley  
Chief Operations Officer, QP

[daire.begley@cilatus.com](mailto:daire.begley@cilatus.com)  
Mobile: +353 87 916 0818



Nollaig Buckley  
Head of Business Development, QP

[nollaig.buckley@cilatus.com](mailto:nollaig.buckley@cilatus.com)  
Mobile: +353 86 387 0500