INGLASIA
PHARMA SOLUTIONS

Services Catalogue

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About **Inglasia Pharma Solutions**

Whether you require support with a one-off task, or you are looking to engage an external Quality department, we have the knowledge, expertise and personnel to curate and deliver the perfect solution.

We work with Pharmaceutical and Biotechnology clients to help them meet global regulatory authority quality expectations on Good Manufacturing Practice and Good Distribution Practice for medicinal products and medical devices.

We have an extensive team of experienced and trusted Quality professionals, meaning we can always provide the right person for the right task.

Our Values

The lotus flower symbolises **Purity** and **Healing**

Purity means that we work **clearly**, **transparently** and without wasting time, money, or human capital.

Healing represents our focus on the ultimate aim: to ensure patients receive their medication in the **quickest**, **safest** and most **effective** way possible.

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How can Inglasia support your business?

Inglasia can offer a unique and bespoke solution for your quality requirements through a variety of contract models offered.

Inglasia contractors are provided with ongoing professional development and access to the extensive knowledge of the entire team providing our clients with unparalleled value.

Support and management of specific quality projects

- ✓ Implementation of a compliant Quality Management System (QMS)
- ✓ Management and completion of vendor Audit Programme
- ✓ Obtaining a Manufacturers and Importers Authorisation (MIA)
- ✓ Obtaining a Wholesale Dealers Authorisation (WDA(H))
- ✓ Computer System Validation

Professional quality contractors with extensive knowledge and skill sets

- ✓ Responsible Persons (RP) and Responsible Persons for Import (RPi)
- ✓ Qualified Lead Auditors for GMP and GDP
- ✓ Trained Project Managers
- ✓ Six Sigma Experts
- ✓ Business Process Modelling
- ✓ Quality Specialists form Junior to Director level

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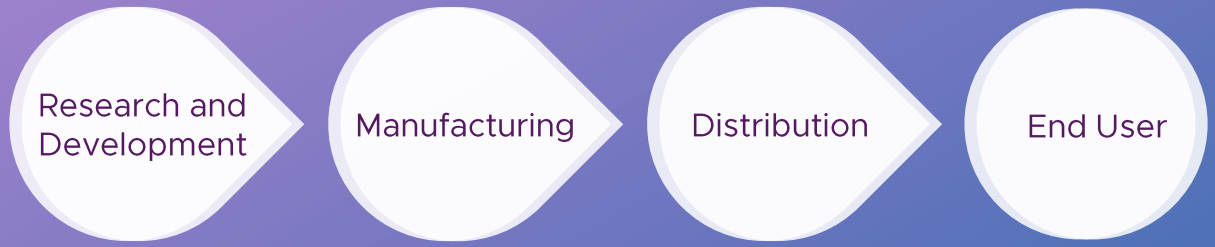
Browse through the QMS support Inglasia offers throughout Medicinal Product and Medical Device Lifecycle stages:

1. Discovery of Molecule
2. Research and Development
3. Investors
4. Materials, Science and Technology (MSAT)*
5. API (Active Pharmaceutical Ingredients)
6. GMP Manufacturer and Marketing Authorisation Holder
7. Fill and Finish
8. CMOs (Contract Manufacturing Organisation)
9. Freight Forwarder/ Transporter/ Brokers
10. Computer Systems Validation Services
11. GDP Warehouse
12. Wholesaler/Healthcare Provider/Pharmacist



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1. Discovery of Molecule – Quality System

- Ensure Good Documentation Practices are adhered to;
- Implementation of Quality System
- Maintenance of Quality System to give structure to operational activities
- Monitor any outsourced activities of product development to ensure the quality of data gathered
- Identify improvements for scale up.

2. Research and Development – Quality System

- Ensure Good Documentation Practices are adhered to;
- Support product quality monitoring throughout development to establish control strategies for manufacture
- Monitor any outsourced activities of product development to ensure the quality of the data gathered and provide more structure to the development studies
- Manage Quality of outsourced clinical trial studies and small-scale clinical manufacturing of investigational medicinal product
- Identify any improvements on the robustness of the scaled-up manufacturing process
- Support in obtaining a manufacturing licence for investigational medicinal product
- CMC Chemistry, Manufacturing and Controls – Training – Quality viewpoint (for lab scientists)
- Good documentation practice training and GMP- developing mindsets – adhere to regs in labs
- First 100 days of QMS.

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3. Investors – Quality Input

- Provision of expert Quality advice with regards to potential acquisitions
- Advice on timelines – what licences are required? Timelines and inspection-readiness support
- Performance of due diligence GMDP Quality audits
- Provision of outsourced integrated “in-sourced” Quality function for small start up businesses – facilitating an asset-light model
- In-sourced Quality function will grow with the business, thereby expending only minimal resources on Quality before product is commercialised
- Fixed fee charged for in-sourced model for 3 or 6 or 12 month contract depending on anticipated growth or business needs.

4. MSAT – Quality System

- Ensure Good Documentation Practices are adhered to;
- Support product quality monitoring throughout development to establish control strategies for manufacturing
- Monitor any outsourced activities of product development to ensure the quality of the data gathered and provide more structure to the development studies
- Manage outsourced clinical trial studies and small-scale clinical manufacturing of investigational medicinal product
- Identify any improvements on the robustness of the scaled-up manufacturing process
- Support in obtaining a manufacturing licence for investigational medicinal product
- Liaising with MSAT around documentation
- Batch record approvals (Approving processes behind the science).

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5. API (Active Pharmaceutical Ingredients) – Quality System

- Ensure Good Documentation Practices are adhered to;
- Auditing of contracted API manufacturer
- Implement QMS for API manufacturing
- Inspection readiness
- Support with obtaining GMP license
- Inspection remediation work.
- Data analysis
- Auditing raw material suppliers
- Clinical technical document review
- Initiate Gap assessment
- Obtaining Quality Buy-in and implementing cross functional working practices
- Perform Product Quality Reviews
- Perform Management reviews
- Licence and registration variations – Quality input
- CSV lifecycle development
- Writing site master files
- Performing temperature mapping studies
- Generation of Validation Masterplan/ protocol
- Writing Quality manuals.

6a. GMP Manufacturer – Quality System

- Ensure Good Documentation Practices are adhered to;
- Supporting with regulatory inspections
- Initial qualification of equipment
- Writing or updating Site Master File
- Writing Business Continuity Plans
- Validation of equipment
- Computer Systems Validation
- Clean room validation
- QMS Support for Aseptic manufacturing processes/steriles
- Project management – e.g. setting up new facilities/ clean rooms/ bringing in fill & finish lines
- Process mapping
- Aseptic process simulation
- Cleaning validation
- Risk assessment
- Personnel training
- Good Documentation Practice training
- Regulatory Inspection-ready and support/ pre- inspection training.

Return to services list

6b. Marketing Authorisation Holder – Quality System

- Ensure Good Documentation Practices are adhered to;
- Quality input in setting up supply chain of product/ product movement
- Working with Regulatory affairs, providing quality checks in creating Regulatory dossiers
- Auditing outsourced functions
- Management of 3rd party suppliers – initial qualification and maintenance
- Management of complaints
- Recalls management.
- Ensure Good Documentation Practices are adhered to;
- Maintenance of QMS as an integrating outsourced service: Inglasia Insourcing
- Inspection readiness support
- Process mapping
- eQMS implementation
- Support with clearing Deviation backlogs/ CAPAs
- Support with WDA or MIA applications
- Act as RP/RP(i)
- Quality input with variation applications/ licences
- Quality support with Strategy.

7. Fill and Finish – Quality System

- Project Manage new Fill and Finish Lines (Quality perspective)
- Quality review of documented evidence of IQ (Installation Qualification) OQ (Operational Qualification) and PQ (Performance Qualification)
- Requalification reviews & able to perform the requalification of closed isolator systems
- Writing of Batch records in conjunction with MSAT and Manufacturing
- Review of Batch records
- Review of all Fill and Finish completed documentation
- Label management / Control
- Isolator Technology Workshop training.

8. CMOs– Contract Manufacturing Organisation - Quality System

- Management and Approval of CMO's (Contract manufacturing organisation)
- Tech transfer (Quality perspective)
- Write / review Quality Technical Agreements
- Quality point of contact for the clients
- Auditing of CMO's
- KPI monitoring for the client.

9. Freight Forwarder/ Transporter/ Brokers – Quality System

- Any company that intends to store or transport medicinal products
- Any freight forwarder that moves medicinal product by road, air and ocean.
- Implementation of QMS to support GDP certification
- Maintenance of QMS as an integrating outsourced service: Inglasia Insourcing
- Supplier approvals
- New customer approvals
- Checks/ correspondence with relevant regulatory bodies – Home Office/ Internationally.
- Any company that intends transport medicinal products
- Temperature mapping of vehicles
- GDP Training of drivers
- Conducting risk assessments
- Temperature excursion investigations
- Temperature excursion training
- Reporting requirements in event of Deviation investigations e.g. length of temp excursion time; range of temperature excursion
- Ensuring correct vehicle types are used (e.g. Cannot use curtain-sided vehicles)
- Maintenance of CMR documents (used when moving product from one vehicle to another).

10. Computer Systems Validation Services – Quality System

- Create a GDP compliant Computer Systems Validation Lifecycle Framework that can be incorporated within the QMS:
  - CSV Lifecycle SOP
  - CSV system-specific templates:
    - Validation Plan, URS, Traceability Matrix, Data Migration Plan, Functional Risk Assessment (look to incorporate current FMEA approach where possible), Functional Specification, Design and Configuration Specification, I/O and PQ and Validation Summary Report
- CSV generic deliverables: desktop audit template and systems register.

11. GDP Warehouse – Quality System

- Any company that intends to store or transport medicinal products
- A wholesaler intending on buying or selling medicinal products as the company will require a wholesale licence to trade
- Any company that stores medicinal product in their warehouse
- Any warehouse intending on performing repackaging activities of medicinal product
  - Mock recalls performed
  - Support with Comparator sourcing and repackaging
  - Supporting warehouse staff with Quality issues
  - Documentation reviews – ensure correct versions in use.

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11. GDP Warehouse – Quality System

- Performing external audits
- Assistance with implementing post audit CAPAS
- Refresher training and new starter GDP training
- Check of Supplier database to ensure correct licences in place
- GAP assessments
- Responsible Person services
- RP/RPi Services
- Home office applications and renewals
- Destruction/ obsolete medicines disposal sign off
- Internal audits/ self inspections
- Trending analysis – secondary packaging.
- Deviations
- CAPAs
- Change controls
- Gap analysis
- Validation projects – (URS, DQ, IQ, OQ, PQ, VSR)
- Temperature mapping of premises and equipment
- Setting up designated controlled areas for Controlled drugs
- Obtaining Wholesale Dealer Authorisations
- Mock regulatory inspections.
- SOP writing and review
- Supplier Management, Bona fide checks
- Building process risk assessments
- Staff training implementation and management
- Implementing eQMS
- Support with managing transition from paper-based to electronic system
- Continuous improvement measures based on trending data
- Ensuring security measures are GDP compliant – reject areas.

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12. Wholesaler/ Healthcare Provider/ Pharmacist - Quality System

- GDP Compliance – Gap Assessment
- Support with WDA application
- Full validation package for warehouse (URS, DQ, IQ, OQ, PQ, VSR)
- Inspection readiness support – mock regulatory inspections
- Hosting client Quality audits
- Implementing and management of QMS
- In-sourced model for QMS support (integrated outsourced function)
- Temperature mapping service
- Management of recalls and performance of mock recalls.
- SOP writing and review
- Supplier Management, Bona fide checks
- Building process risk assessments
- Staff training implementation and management
- Implementing eQMS
- Support with managing transitions from paper-based to electronic system
- Continuous improvement measures based on trending data
- Ensuring security measures are GDP compliant – Reject areas
- Provision of GDP training
- Ensure Good Documentation Practices
- Implementing QMS – where required.

At Inglasia Pharma Solutions,
we are here to **meet your**
Quality needs