Pharmaceutical Solutions Ltd

HOW WE CONDUCT OUR BUSINESS

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Pharmaceutical Solutions Ltd is a quality-led organisation, specialising in the provision of professional QP services and the certification of medicinal products for use within the EU.
To do this we follow a simple 3-step process for new jobs: Enquiry – Quotation – Acceptance

ENQUIRY:
From an initial enquiry, one of our QP's will follow up to obtain a detailed overview of the job.

Key points concern where the job is located, a breakdown of all parties involved, their locations and responsibilities, the term of the job, product types concerned and responsibilities / duties required of Pharmaceutical Solutions Ltd or our approved service providers.

For new customers / significant projects it may beneficial to meet in person.

As well as considering your needs, we may also need to consider the requirements of our own licenses and those of our QP's, particularly where formal batch certification is involved, since the QP's will need to gain familiarity of the manufacturing stages to be certified and the supporting quality systems.

We also appreciate that confidentiality agreements may need to be established at this stage.

QUOTATIONS
Pharmaceutical Solutions Ltd will provide a quotation once we have a detailed understanding of the project and the scope of work has been defined.

Where necessary Pharmaceutical Solutions Ltd will liaise with our own approved suppliers to obtain accurate costs and timelines concerning any packaging, testing or physical handling of the products.

ACCEPTANCE
Once the quotation is formally accepted Pharmaceutical Solutions Ltd will work with you to finalise commercial and technical agreements and any final details of the working arrangements.

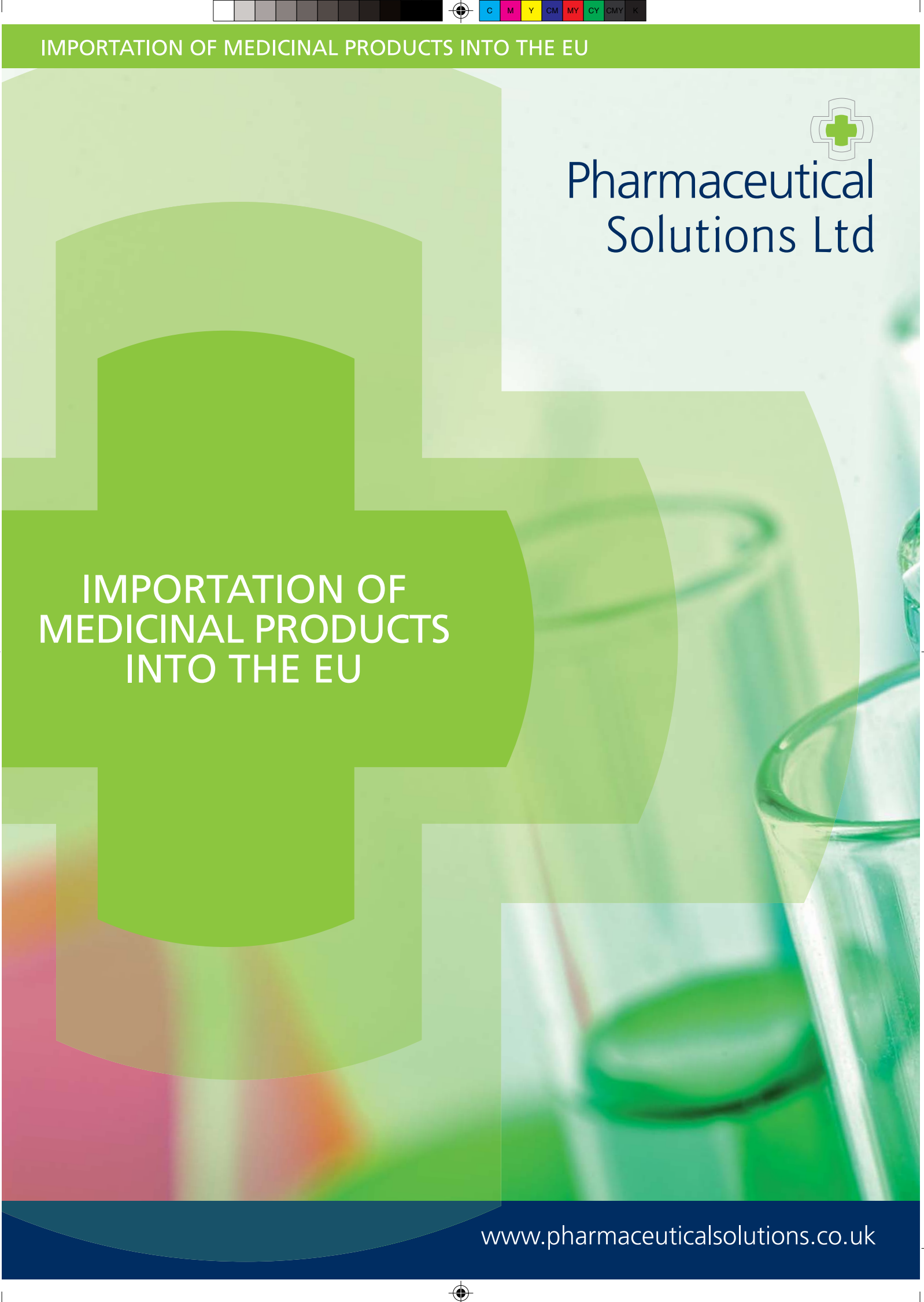
Where necessary, Pharmaceutical Solutions Ltd will provide copies of CV's, Certificates of QP-eligibility and signed nomination forms in order to support necessary licensing requirements.

All that remains is to start the job.

...serving the pharmaceutical industry

Pharmaceutical Solutions Ltd

IMPORTATION OF MEDICINAL PRODUCTS INTO THE EU



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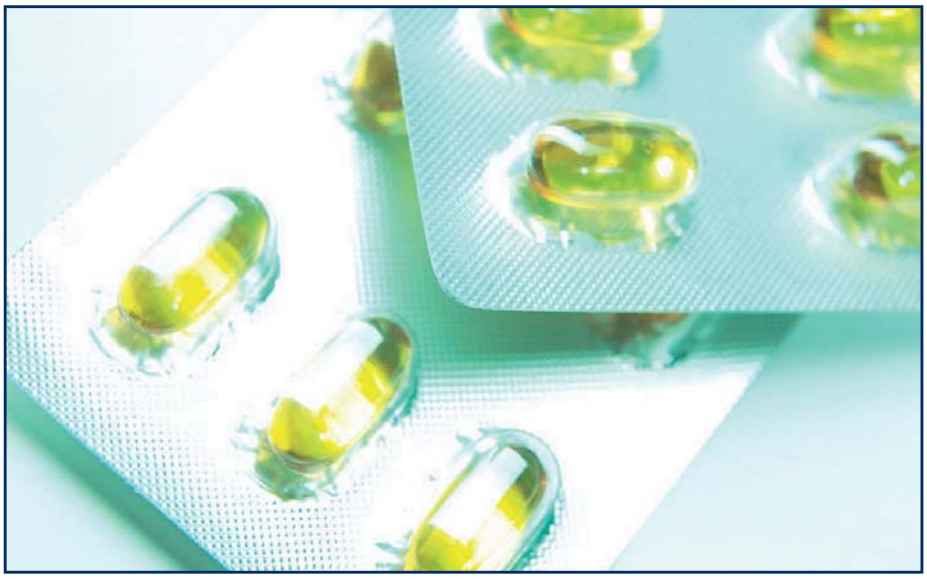

This novel business model not only ensures the involvement and availability of a Qualified Person (QP) for product release – but ensures the QP is involved at all stages from project initiation and start-up activities through qualification of the manufacturing & supply chain to batch certification and release.

The role of Pharmaceutical Solutions Ltd is as follows:

Oversee importation and release activities (from outside EU) for bulk or finished medicinal products

For commercial supply

For investigational use (Investigational Medicinal Products – IMP's)

Maintenance of UK licenses and contracted services:

Pharmaceutical Solutions Ltd holds its own MHRA licenses for Importation and Release of medicinal products

Commercial bulk or finished products

Investigational Medicinal Products (IMP's) for assembly or as finished kits

Pharmaceutical Solutions has formally approved sub-contractors for warehousing and distribution and for analytical testing upon importation

Manufacturing and Supply Chain Qualification

Once we understand your manufacturing supply chain, we can:

Conduct QP audits of your chosen manufacturing facilities (API, manufacturing, packaging and analytical testing facilities)

Plus, for imported bulk products:

Recommend pre-qualified UK packaging facilities

Recommend pre-qualified analytical test laboratories (for importation testing)

Arrange and project manage the receipt, packing, testing and QP-release of your products

OR, for imported finished products:

Recommend pre-qualified analytical test laboratories (for importation testing)

Arrange and project manage the receipt, testing and QP-release of your products

Post-Release Services

Assist with deviations, complaints and recalls as necessary

Assist with annual product reviews

Assist with regulatory variations, license extensions and new applications

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PRODUCTS OF FAMILIARITY

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Our Qualified Persons (QP's) have in excess of 15 years individual service within the pharmaceutical industry. Coupled with experience in a wide variety of areas including R&D, manufacturing, packaging and contract services, each QP is able to provide general support, including batch certification for a wide range of medicinal product formats, whether intended for investigational (clinical) or commercial use. Areas of familiarity include the following

Sterile Products

Terminally sterilised

Aseptic

Lyophilised

Solid Oral Products

Tablets & Capsules

Softgels

Rapid dissolve tablets

Lozenges

Liquids, Creams and Ointments

Inhaled Products

Metered Dose Inhalers (MDI)

Dry Powder Inhalers (DPI)

Medical Gases

Skin Patches

Vaccines and Biopharmaceuticals

Veterinary Products

Stability lots, pilot scale, clinical scale or commercial scale

Assembly Operations

(commercial or clinical scale)

Blisterpacking

Bottle filling

Strip packs

Sachet filling

Labelling

Overwrapping

Cartonning

Hand assembly

Assembly of patient kits for clinical trials including randomized supplies

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CONSULTANT QUALITY AND QUALIFIED PERSON SERVICES

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Pharmaceutical Solutions Ltd specialises in the provision of professional quality / Qualified Person resource. Our flexible yet experienced approach lends itself to meeting your business requirements including long or short term contracts, for infrequent periods, regular monthly periods or regular weekly periods.

Provision of Qualified Person Resource:

Review, certification and release of all major dosage forms

QP-Certification, release or advice

Experience in QP release of medicinal products imported from 3rd countries

General QP oversight and support

Investigational Medicinal Product (Clinical Trial Supplies) Expertise:

Phase I to IV trials

Importing from non-EU countries

Sterile Product Expertise:

Including blow-fill-seal technology

Facility, process pipework and vessel design

Equipment assessment and specification

Facility Auditing / Supplier Management:

Active pharmaceutical ingredient (API) manufacturers

Excipient and component suppliers

Contract manufacturing, packaging or testing facilities

Assistance with general contract manufacturing outsourcing

Facility Preparation & Readiness in Support of:

Gaining new manufacturing authorisations / product license approvals

Routine regulatory inspections

Product license variations

Self inspections, customer audits and corporate audits

Project Management

Design and documentation of Quality Systems

Inspection preparation

New product introductions

Ongoing and routine activities and Quality System Management

Quality System Support

Deviations / non-conformance

Complaints and recall

Supplier Management

Standard Operating Procedures

GMP training

Validation

Self inspection

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