Woodley BioReg Limited

Company and Services Overview

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Woodley BioReg Limited – Presentation Overview

- Company Background and its Spheres of Influence
- Services
  - Regulatory Affairs
  - Quality Assurance and GMP
  - Import Services (into the UK and EU)
  - Training Services
- Areas of Expertise
  - Examples of Products Registered and Maintained by WBR
- Examples of Current Global Projects

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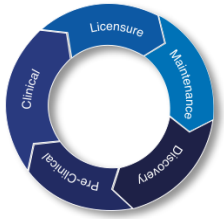
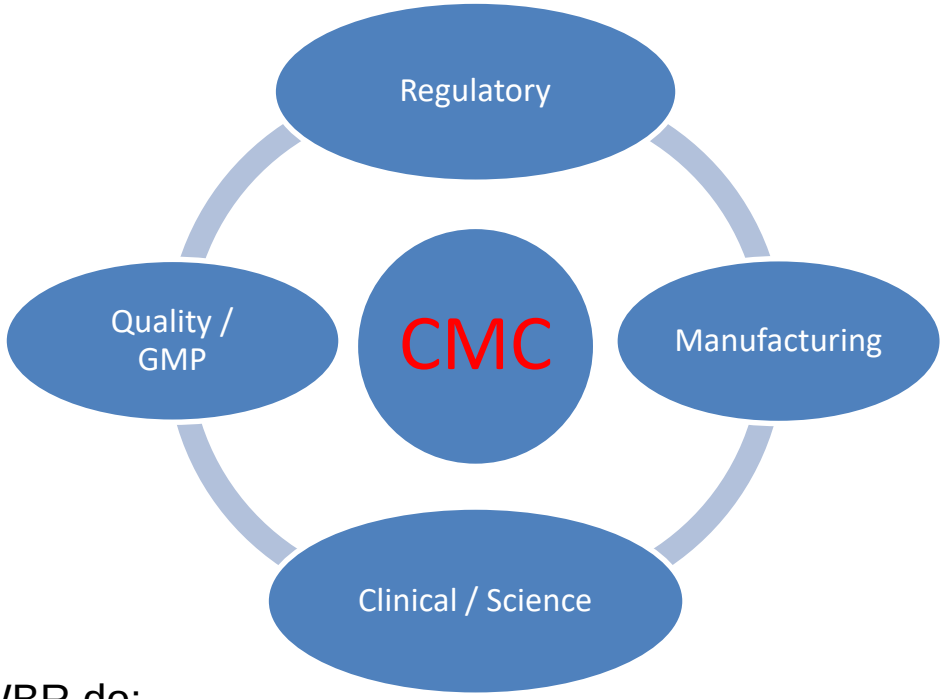


Company Background

- Established in 2000, incorporated in England & Wales in 2001
- Headquarters in the UK
  - With offices in Poland, S. Korea, USA, China and India (Italy, Germany)
- cGMP certified by MHRA (since 2015)
- Permanent employees supplemented by a network of Specialist Associates
- Operate Globally
  - Europe, USA, India, China, South Korea, Australia……..

WBR Spheres of Influence



- What do WBR do:
  - Help manufacturers **develop** and **successfully register** drugs **globally**
  - Support our clients to operate to full **cGMP** (including WHO, ICH, PIC/S)
  - Facilitate and support **organisational change** and development at all levels

- Develop strategies and opinions that provide a consensus framework and leadership to the industry
  - Biosimilars
  - Licence maintenance / global lifecycle management

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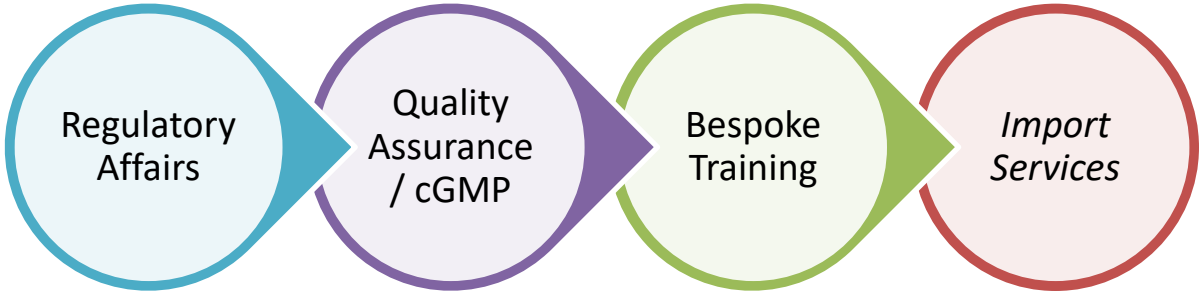
WBR Core Services

- Provide Regulatory, Quality, Training and Import Services



- Work with the manufacturers and suppliers of:
  - Biopharmaceuticals / biologics / biosimilars
  - Pharmaceuticals
  - Generics
  - Healthcare / Over-the-Counter Medicines
  - Active Pharmaceutical Ingredients (APIs)
  - Medical Devices / Combination Products

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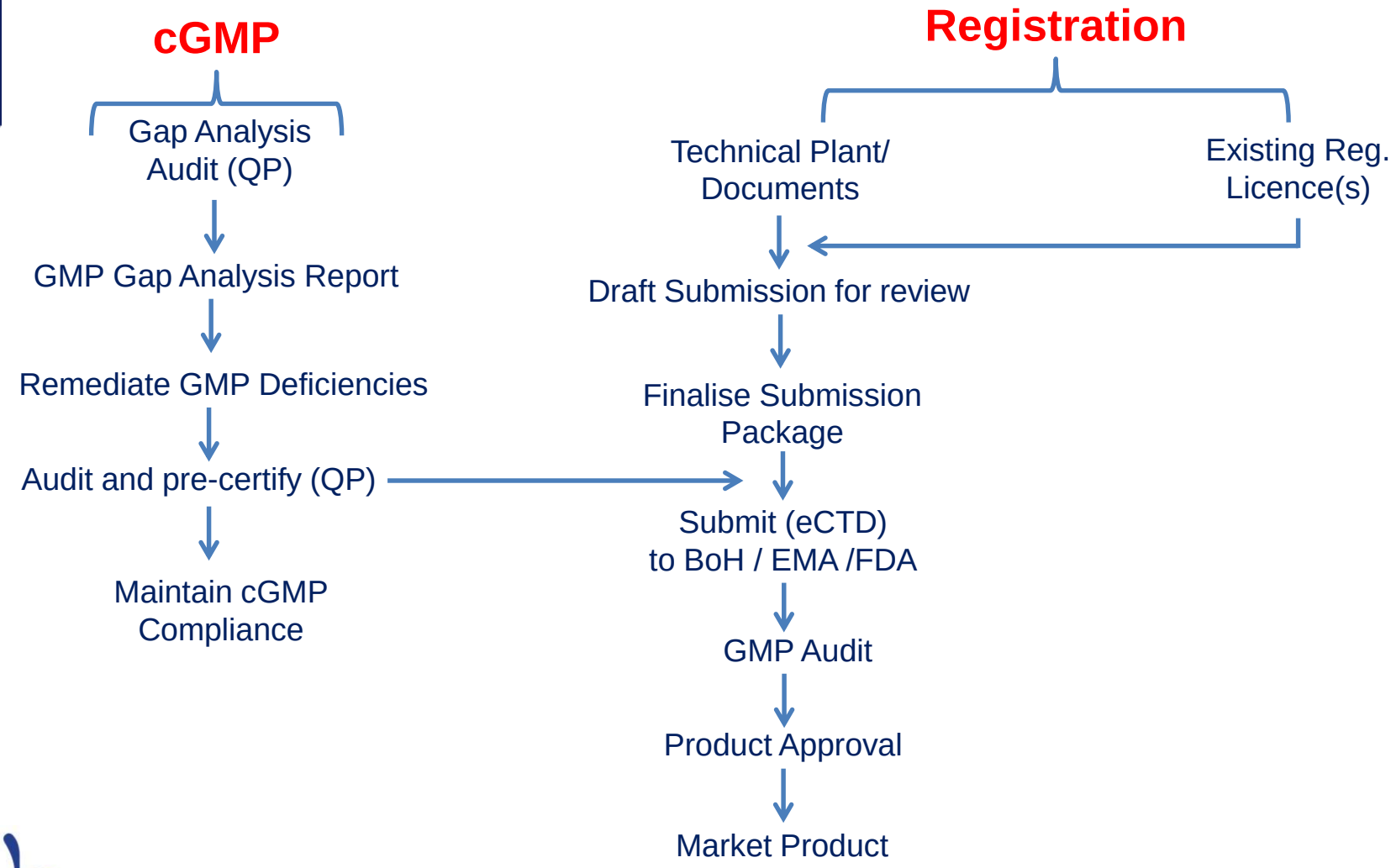
Overview of EU / US GMP and Registration Process



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What does Woodley BioReg do?

- **Quality Assurance**
  - We assess pharmaceutical manufacturers to global / GMP compliance
  - We work with manufacturers to develop remediation plans to fix deficiencies
    - Facilities, Utilities, Documentation / QMS, Training, Validation, etc
  - Our QPs pre-certify manufacturers and guarantee their formal certification
  - We will trigger GMP inspections (without MA submission)
  - If needed, we provide full Quality Assurance and caretaker services within the UK and EU
  - Provide EU / UK PV and QPPV support

- **Regulatory Affairs**
  - Develop submission strategies and roadmaps UK / EU authorisation
  - Undertake all activities to prepare / update and review the MA
  - Submit the MA on behalf of our clients
  - Respond to agency questions
  - Maintain the licence(s) post approval

What does Woodley BioReg do?

- **Other Post Approval activities**
  - Importation of non-EU / UK products using WBR's MIA / WDA licences
  - Import testing for non-EU / UK manufactured products
  - QP release
  - Quality Management System (QMS) implementation / maintenance

- **Supplementary Support activities**
  - Access to WBR clinical support (for all m5 related activities)
  - Access to WBT toxicologists (for all m4 related activities)
  - eCTD publishing
  - Use of WBR UK / EU offices for company registration / MAH responsibilities
  - Auditing
  - Training – bespoke training to ensure GMP compliance and local empowerment

The following slides provide further details of some of these support activities

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Regulatory Affairs Support – *Flexible Resourcing*

- **Flexible Resourcing – applies to all WBR operations**
  - Day-to-day support for functional activities; 1 FTE split over 2-3 roles
  - Qualified resources with 2 to 25+ years of experience
  - Ex-Industry, ex-Agency (MHRA, HPRA, BfArM, EMA, Health Canada, FDA, etc.)

- **Submission Strategy Development**
  - Specifically tailored to product and client goals; using over 500yr collective experience
  - DCP / MRP / CP / duplicate licences / COO etc.

- **Marketing Authorisations / Product Licences Preparation**
  - m1 through to m5
  - eCTD publishing

- **Agency Meetings** (Scientific Advice, Pre-IND, Orphan, ATMP)
  - Respond to Requests for Information **(RFIs**)

- Licence Maintenance / Life-Cycle Management
  - Change of ownership, Variations, Renewals, etc

- Provide **EU Regulatory Affairs office** for overseas (non-EU) clients
  - Regulatory Affairs, QMS, QP, PV / QPPV, clinical / nonclinical, etc

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Quality Support

- **cGMP** standards and certification (EU and US)
  - Contract QP services (biologics and pharmaceuticals including steriles)
  - Full validation and documentation assessment and remediation / re-writes
  - Provision of WBR EU-registered QP certificate
- **Quality Management / Quality Assurance System**
  - Development, refinement/ amendment and deployment of QMS
  - ISO 13485 (medical devices)
- **Pharmacovigilance**
  - Full PV including contract QPPV services
- **Auditing**
  - Self-Audits
  - Due diligence
  - Third party manufacturers
  - Remediation plans and assistance
- **Investigations**
  - Failures, OOS, Deviations, Recalls, post-change impact assessments
- **Training**
  - GMP

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Import Services (Supplementary Service)

- Allows non-EU manufacturers to make a soft landing for EU commercialisation
- Provide **EU address**
- Laboratory **Testing Services**:
  - Full batch release testing
  - Identity testing
  - Product quality specification (PQS)
  - Stability - storage (temperature and humidity controls) and stability indicating assays
- **QP sign-off for batch release**
- **PV contact** for Adverse Event reporting (see later)
- Secure, controlled **storage** of GMP pharmaceutical products
- **Shipping and distribution** within the EU
- All EU legal requirements governed by WBR's MHRA approval
  - Manufacturer's Importer's Authorisation (**MIA**)
  - Wholesale Dealers Licence (**WDL**)

Clinical and Nonclinical

- **Nonclinical**
  - Toxicological assessments
  - BE study protocols and approval
  - Preparation of m4 sections and m2 nonclinical summaries
  - Nonclinical expert / sign-off
  - Wide range of APIs and finished formulations covered

- **Clinical**
  - Development, review, and approval of Clinical Protocols
  - Clinical Trials management (up to n=50)
  - Clinical data assessment
  - Preparation of m5 sections and m2 clinical summaries
  - Clinical / Medic sign-off
  - Biologics / biosimilars, pharma / generics, and Medical Devices / combination products

Training Services, example courses

- Delivered locally, internationally or at client sites
- Tailored to meet client-specific requirements, including workshops / tests
- Quality
  - cGMP and Quality Systems Requirements
  - How to Audit to cGMP - what to look for in self-audits
  - Pre-approval Inspection Requirements for the US FDA, EMA and MHRA
  - cGMP Documentation Requirements and Preparation
- Regulatory
  - Regulatory Affairs Submissions
  - New Variation Guidelines
  - Introduction to European Regulatory Affairs
  - How to Register Biosimilars to “Global Standards”
  - Regulatory requirements for APIs
  - Regulatory Requirements for Medical Devices, include Combination Products
- Others
  - Identification and Validation of Critical Manufacturing Process Steps

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Pharmacovigilence Support

- **EU QPPV Provision through an EU authorised provider**
- Pharmacovigilance System Master File (**PSMF**)
  - generation and maintenance
- Receipt and processing of Serious Adverse Events (**SAE**) onto ARISg
- Medical Review of ADR reports and submission of expedited reports
- Literature searches (required for **PV reporting**)
- Periodic Safety Updates (**PSURs**)
  - preparation and distribution of Risk Management Plans (**RMPs**)
- Signal detection
- EVMPD (PV database) maintenance
- Audits and training

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Areas of Expertise

- Biologics / Vaccines
- Biosimilars
- Pharmaceuticals / Generics
- Healthcare / OTC
- Devices (including Drug Device combinations)

- Steriles including pre-filled syringes
- Advanced Therapeutic Medicinal Products (ATMPs)
- Orphan Products
- Metered Dose Inhalers
- Solid dose, gels, and capsules
- Topicals (creams and ointments)

- Opinion and consensus development for Industry leadership
- Organisation change implementation

Products WBR have Registered and Maintained

Examples of products WBR registered and maintained in the EU and US:

- Analgesics
- Anti-anxiety
- Antibiotic
- Anticholinesterase
- Anticonvulsants
- Antidepressants
- Anti-epileptic
- Antihypertensive
- Antihistamines
- Anti-platlets
- Antipsychotic
- Bi-phosphonates
- Cholinesterase Inhibitors
- Diuretics
- Immunosuppressants
- Laxatives
- Leukotriene Receptor Antagonists (Asthma)
- Meglitinides (Diabetes)
- Oncology
- Proton Pump Inhibitors
- Sedatives
- Statins
- Steroids
- Vaccines
  - Anthrax
  - Diphtheria
  - Hepatitis B
  - Influenza
  - Meninge
  - Pertussis
  - Tetanus
  - Typhoid
  - Yellow Fever
- Vitamin D products

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Example Projects

- EU and US Registrations
  - Statins / Anti-depressants / Anti-hypertensives / Analgesics / Combination products / Vaccines etc.
  - For Chinese and Indian generics manufacturers
  - WEU application for an EU client
  - Parallel Importation licence assessment and registrations
- EU Regulatory and Quality department
  - Long-term provision of EU “virtual” regulatory department for an Indian generics manufacturer
- Quality Management System (QMS) implementation
  - Scoping, writing, implementation and ongoing management of a QMS for the UK division of a Chinese international generics manufacturer
- Global Conformance Review
  - Review of >2,000 over-the-counter healthcare products for a multi-national pharmaceutical company
- Quality Audit of a Manufacturer
  - Due diligence audit of a Korean biologics manufacturing company prior to US acquisition

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