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Applying for a Wholesale Distribution Authorisation WDA(H)

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Distributing Pharmaceuticals 2023

Learning outcomes

- Understand the basic regulatory requirements of a Wholesale Distribution Authorisation for human medicines
- Gain insight into the resources and time required to remain compliant
- How a Wholesale Dealer's Licence could benefit your existing business
- How SeerPharma UK can help you.

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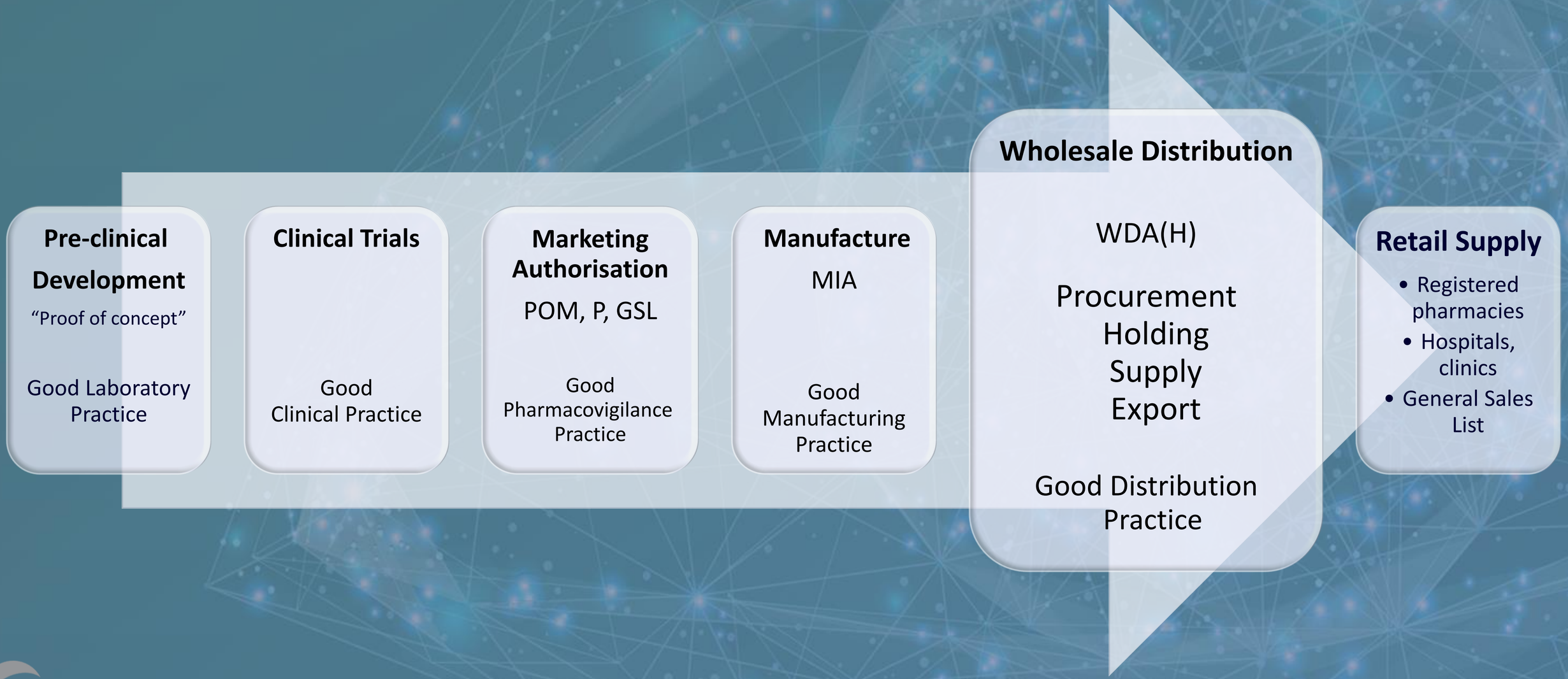
The product lifecyle and compliance



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Current legislative framework

UK legislation

- Human Medicines Regulations 2012 (HMR 2012)
- consolidated from the Medicines Act 1968, enacted in 2012 and amended since
- Part 3 of the HMR 2012:
  Chapters 1A & 2 relevant to Manufacture and Wholesale Dealing of medicinal products
  Chapter 3 deals with Brokering of medicinal products
  Chapter 4 deals with manufacture, importation & distribution of Active Substances

Good Distribution Practice

- Guidelines on Good Distribution Practice (HMR 2012 Reg. C17)
- The licence holder must comply with Good Distribution Practice (HMR 2012 Reg. 43(1)).

What is wholesale distribution?

(4) In these Regulations a reference to distributing a product (including a listed NIMAR product) by way of wholesale dealing is a reference to—

(a) selling or supplying it; or

(b) procuring or holding it or exporting it for the purposes of sale or supply,

to a person who receives it for a purpose within paragraph (5).

(5) Those purposes are—

(a) selling or supplying the product; or

(b) administering it or causing it to be administered to one or more human beings,

in the course of a business carried on by that person.

HMR 2012, Regulation 18

Visit www.legislation.gov.uk

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When is a WDA(H) required?

- referred to as a Wholesale Dealer's Licence in UK law, and commonly known as a "WDA(H)"

- Any legal person (individual or body corporate) within the UK involved in the wholesale distribution of medicines for human use must hold a WDA(H) granted by the UK Licensing Authority.

- A WDA(H) permits the importation of medicines from "approved countries for import" if there is a named Responsible Person (Import) (RPi) on the licence

Requirements for a WDA

- WDA(H) holders can only supply manufacturer's original packs, they cannot apply a label or otherwise change the product's primary or secondary packaging.

- A WDA(H) will list the types of products permitted to be wholesaled and activities, along with sites from which the holder carries out their activities.

- Procurement of medicinal product from a third country, for direct supply to a third country, requires a WDA(H) even if those products do not enter the UK (known as "Introduced" medicinal products).

Named persons on a WDA(H)

Licence Holder

- The Licence Holder has many obligations:
  - Appoint a competent and knowledgeable RP, who is continuously available
  - Develop a quality management system
  - Provide and maintain adequate staff, premises, equipment & facilities for the handling, storage and distribution of medicinal products
  - Only buy from and sell/supply to authorised persons
  - …

Responsible Person

- Commonly referred to as the “RP”
- The RP has several obligations:
  - Ensure the licence conditions are always being complied with
  - Ensure the quality of medicinal products being handled is maintained
  - The RP must have oversight of all activities and ensure processes are adequate and robust

The licence holder and Responsible Person (RP) are the key figures in a wholesale operation.

Without them, a company is acting illegally and cannot hold the WDA.

Good Distribution Practice

- Commonly referred to as ‘GDP’
- It states in the HMR 2012 that the licence holder must comply with the guidelines on GDP
- Manufacturer’s must also comply with the guideline on GDP, even though they will not usually hold a WDA(H)

But what does this mean?

- The medicines supply chain can be very complex
- The guidelines exist as a minimum set of standards, ensuring that wholesaler distributors carry out their operations safely and consistently, preventing any errors and incidents
- Implementing GDP should mean the distribution chain is controlled, and the quality & integrity of medicines have been maintained.

The ultimate aim of GDP is to protect the patient

Chain of trust

The Patient trusts the Doctor

The Doctor trusts the Pharmacist

The Pharmacist trusts the Wholesaler

The Wholesaler trusts the Manufacturer

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Applying for a WDA

- All applications are to be made on the MHRA process licensing portal. Users must register to use this. *Pclportal.mhra.gov.uk*
- Further guidance is available from:
    - The Process licensing team: pcl@mhra.gov.uk
    - MHRA Guidance Note 6.
    - Rules and Guidance for Pharmaceutical Distributors (the “Green Guide”)
- A new site will be inspected before a licence is granted. The inspection covers the business model, premises and equipment, the quality system, all aspects of GDP **and** makes and assessment of the RP
- The WDA can cover more than one site, so long as they are all the same legal entity; these are given individual site reference numbers
- Reduced application and inspection fees apply in limited circumstances.

Knowledge & experience

Skills & behaviours

Documentation

Staff & Premises

Resources & equipment

Demonstrating compliance

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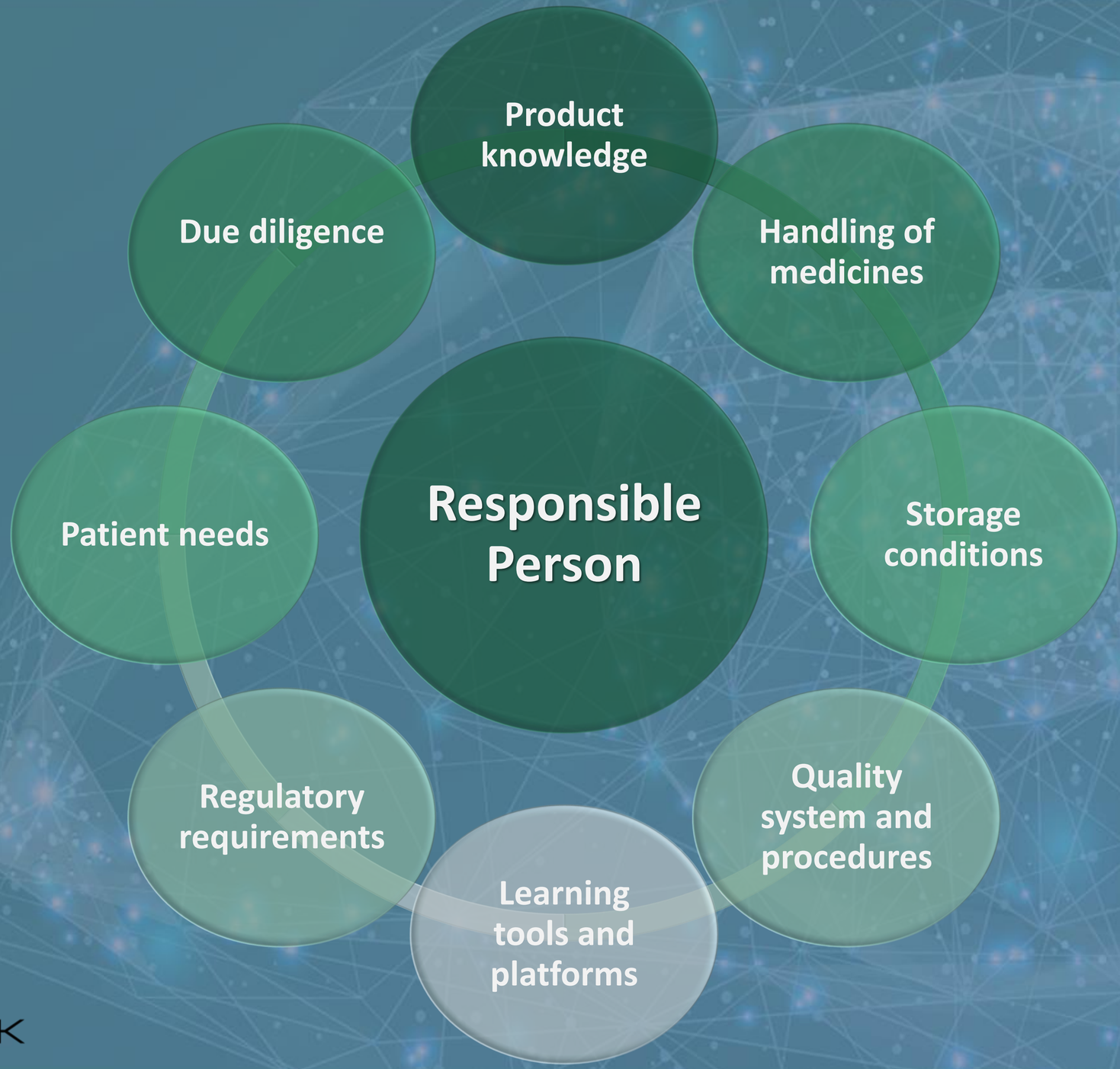

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Enhance your business

- Utilise your current network and contacts
- Build on your existing infrastructure
- Cater to a wider audience – commercially succeed!
- Better meet the needs of the patient via different supply routes
- Broaden your horizons – access new markets

Useful tips

- **Awareness of the regulator and their role**
  - Medicines and Healthcare products Regulatory Agency (MHRA)
    - An executive agency sponsored by the Department of Health and Social Care
    - the “Competent Authority” in the UK for medicines for human use
- **MHRA sources of information:**
  - Blogs, Publications, Guidance Notes, Email alerts
- **International Focus**
  - Learn about other regulators and relevant guidance documents.
- **Events**
  - Engage with industry peers to learn from best practices
- **Training courses**
  - Approved courses delivering bespoke training to meet your learning needs
- **Consultancy services**
  - Tailor-made guidance from experienced consultants to achieve maximum compliance

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Our philosophy

Understanding the regulations is good, but understanding the Regulator is, we believe, the gold standard. As former MHRA inspectors, we have both the insight and practical understanding of the regulatory regime as well as practical knowledge of how those regulations are interpreted.

Our aim

To share that inside knowledge to help you compete successfully in the regulated environments of pharmaceutical, biotechnology, medical devices and related industries.

Meet the Team

Mariam Naqesh-Bandi, Director & Senior Consultant

Shahbaz Sarwar, Director & Senior Consultant

Madeleine Ault, Director & Senior Consultant

Gaynor Brummitt, Director & Senior Consultant

Alan Bentley, Director & Senior Consultant

Debra Stanfield, Office Manager

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… Including Subject Matter Expert Associate Consultants

Consultancy services provided

- Highly tailored and practical advice and solutions to help companies grow their business
- Provide extensive knowledge of the regulatory environment to effectively communicate this to significant figures in industry (licence holder and Responsible Persons)
- Ensure companies have in place the correct quality and productivity tools and techniques required to succeed. So whether that's improving their compliance history with the regulator, differentiating against national and international competition or driving greater profitability from operations, SeerPharma can provide the solutions.
- Have provided services to pharmaceutical businesses ranging across different business models:
  - **Specialised distribution, cold chain, biologicals, marine, aesthetics, freight forwarders, virtual operators, NHS hospitals, manufacturers, pharmacies, UK and Global.**

Training services provided

- Responsible Person Gold Standard training courses held every 4-6 weeks via remote, hybrid and face-to-face
- Training courses available:
  - Export of Pharmaceuticals
  - Quality Risk Management in Distribution
  - Deviation, CAPA and Root Cause Analysis
  - WDA Holder – GDP and Licence Obligations
  - Audit (self-inspection) training
  - Temperature Management
  - Responsible Person Import
  - Principles of Good Distribution Practice
  - Wholesale in Community Pharmacy/GDP for Pharmacists (coming soon)
- Bespoke training tailored to a company's requirements or circumstances.
- Working collaboratively with other training providers, e.g. TOPRA and Key2Compliance
- Coming soon: GDP eLearning.

Any questions?

Let’s chat! Please come and visit us at Stand 203

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