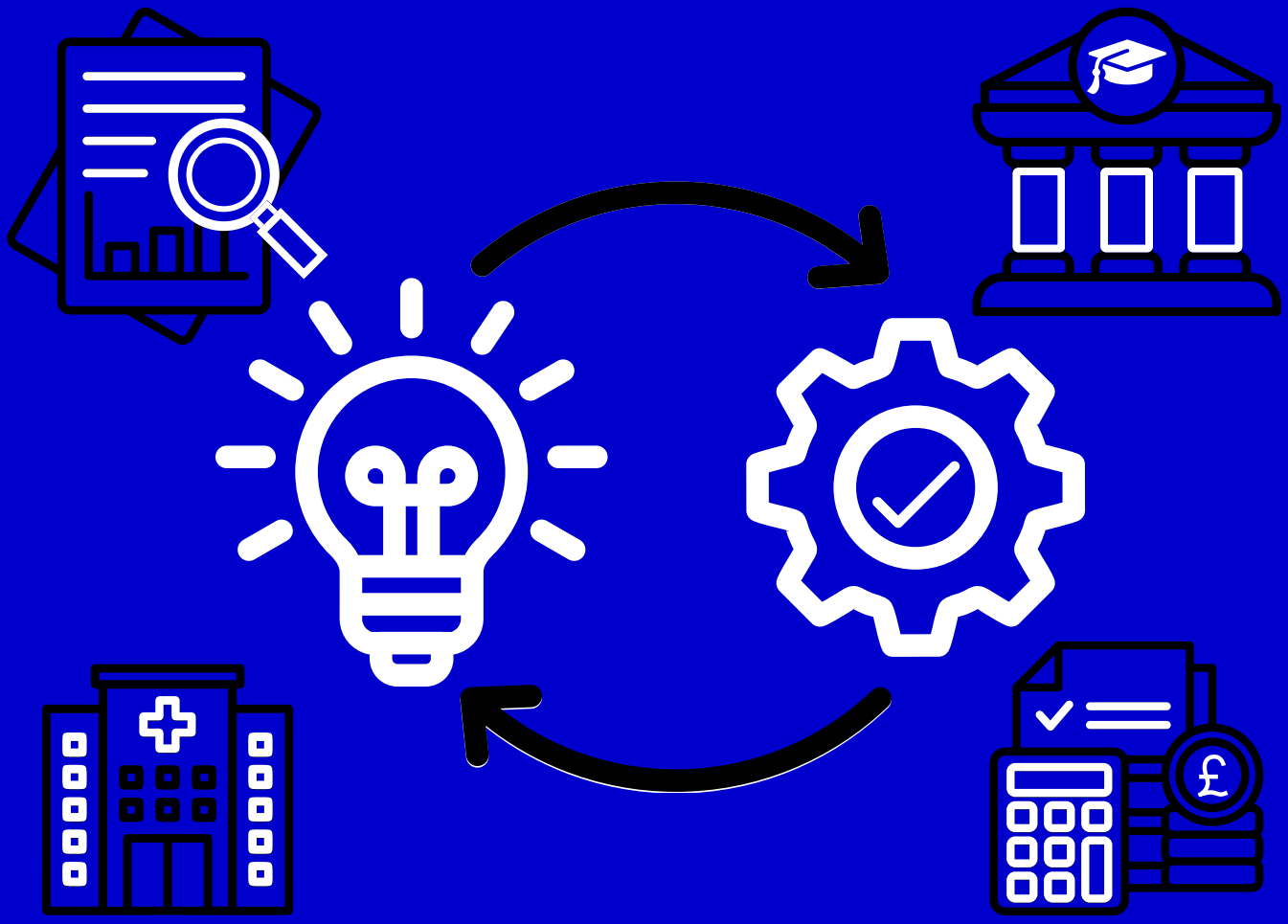
IMPERIAL

MedTechONE

# FROM IDEA TO ADOPTION

PART 2



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COLLABORATIVE

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# FROM IDEA TO ADOPTION

The path to commercialisation is long and complex. From the synthesis of an innovative idea, through testing and iterations, through clinical trials, and through regulatory and commercialisation processes, this set of resources aims to de-mystify some of the key concepts you should be aware of.

As it was too bulky to have all of the information in a single resource, we recommend you read this document alongside the other parts of this piece on the MedTechONE Collaborative webpage.

# LICENSE TO MANUFACTURE & LEGAL MANUFACTURER

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The **"Legal Manufacturer"** is the business or entity that holds full regulatory responsibility for the design, manufacture, and market placement of a medical device. They are also responsible for ensuring full compliance with any applicable regulations and standards.

Core responsibilities for legal manufacturers can include:

- Design and Development of the product, including design phases, validation work, and risk management in relation to regulatory responsibilities and user needs.
- Primary manufacturing and quality control
- Regulatory compliance
- Post-market surveillance
- Labelling and Instructions for Use (IFU)

**"Manufacturer"** is defined as "a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured, or fully refurbished, and markets that device under its name or trademark."

Licenses to Manufacture are issued by the Medicines & Healthcare Products Regulatory Agency (MHRA). The licensing process requires you, or your company, to demonstrate to the MHRA that your processes and product are compliant with EU Good Manufacturing Practice (GMP), and that they pass regular GMP inspections of your manufacturing sites.

You can find more information on applying for a License to Manufacture, and links to start the process, at the full guidance linked in the "Further Reading & Resources" pages of this document.

# LICENSE TO MANUFACTURE & LEGAL MANUFACTURER

**Items to note:**

- Your application will take 90 working days to process.
- Variations to existing licenses should take 30 working days to process, extended to 90 working days if an inspection is required.
- The MHRA will check the identities of the responsible persons and named staff and will check your named company registered with Companies House.
- Inspections will require a Site Master Plan / File for every manufacturing site.

When the Inspectors are satisfied, and any identified issues have been rectified, the MHRA will complete your registration, and you will receive:

- A Licence document
- A Manufacturer's Certificate of Good Manufacturing Process (GMP) for each inspected site
- (For Wholesale Distributors) a Certificate of Good Distribution Practice (GDP) for each inspected site.

**N.B.** This licensing process does incur a fee from the MHRA and requires an annual fee to maintain the licence (in April of each year). You will be sent an invoice annually. The fee is directly related to the type of licence, the number of sites, and the income from any licensed wholesale businesses.

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# CONTACTS

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