Medicines & Healthcare products Regulatory Agency

Decentralised Manufacturing

Point of Care processes

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NHS QA TS Symposium

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The new framework – background

Origin:

- Enquiries received at the Innovation Office and at Scientific Advice Meetings – reviewed as part of horizon scanning for actionable regulatory changes

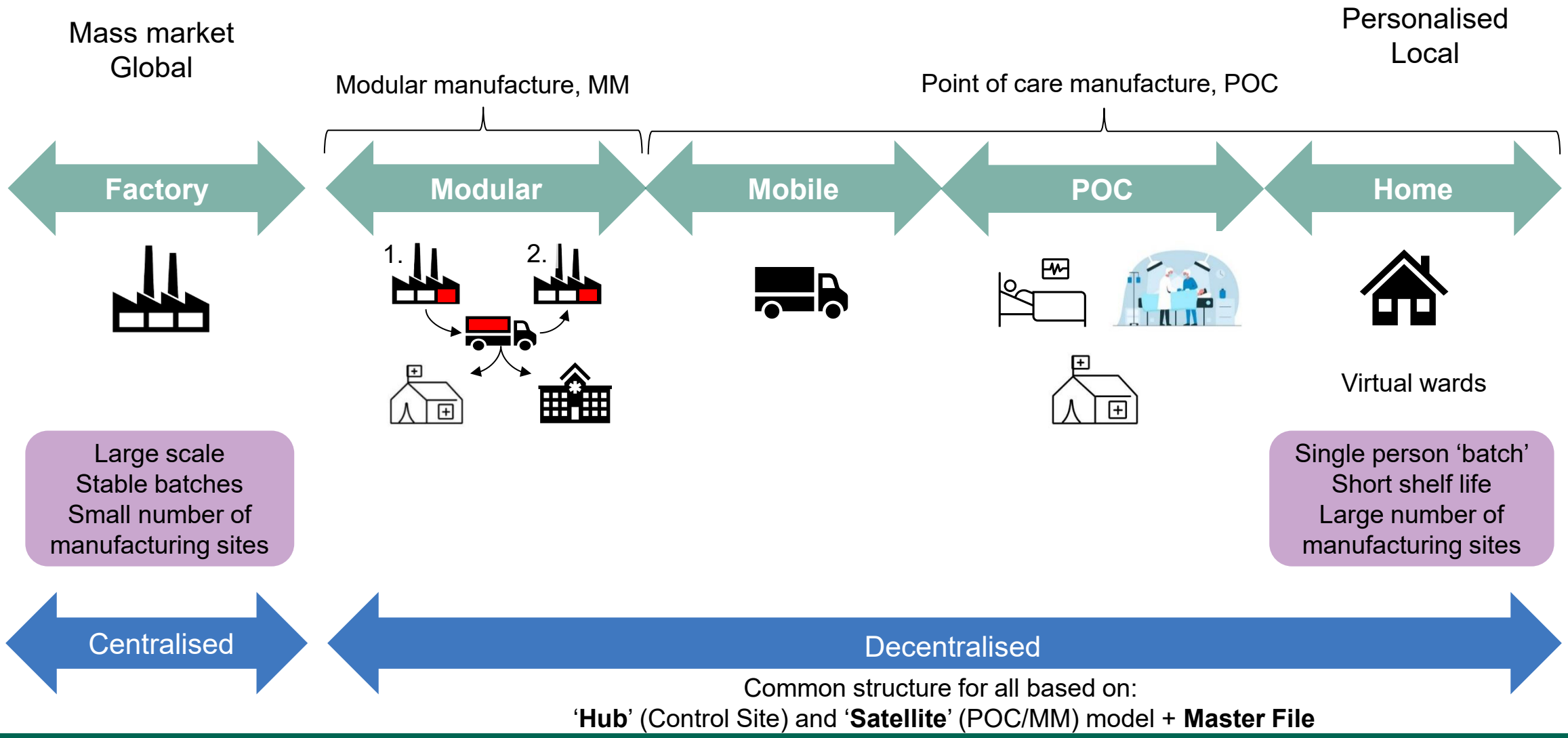
Objectives:

- Supports a broadened range of manufacturing and supply options
- Control measures equivalent to those currently in place to ensure that Point of care (POC) and Modular manufacture (MM) products result in products with equivalent levels of quality, safety and efficacy
- Closely connected to the current framework with legal tests to avoid duplication and confusion
- Accommodates future developments

Applicability:

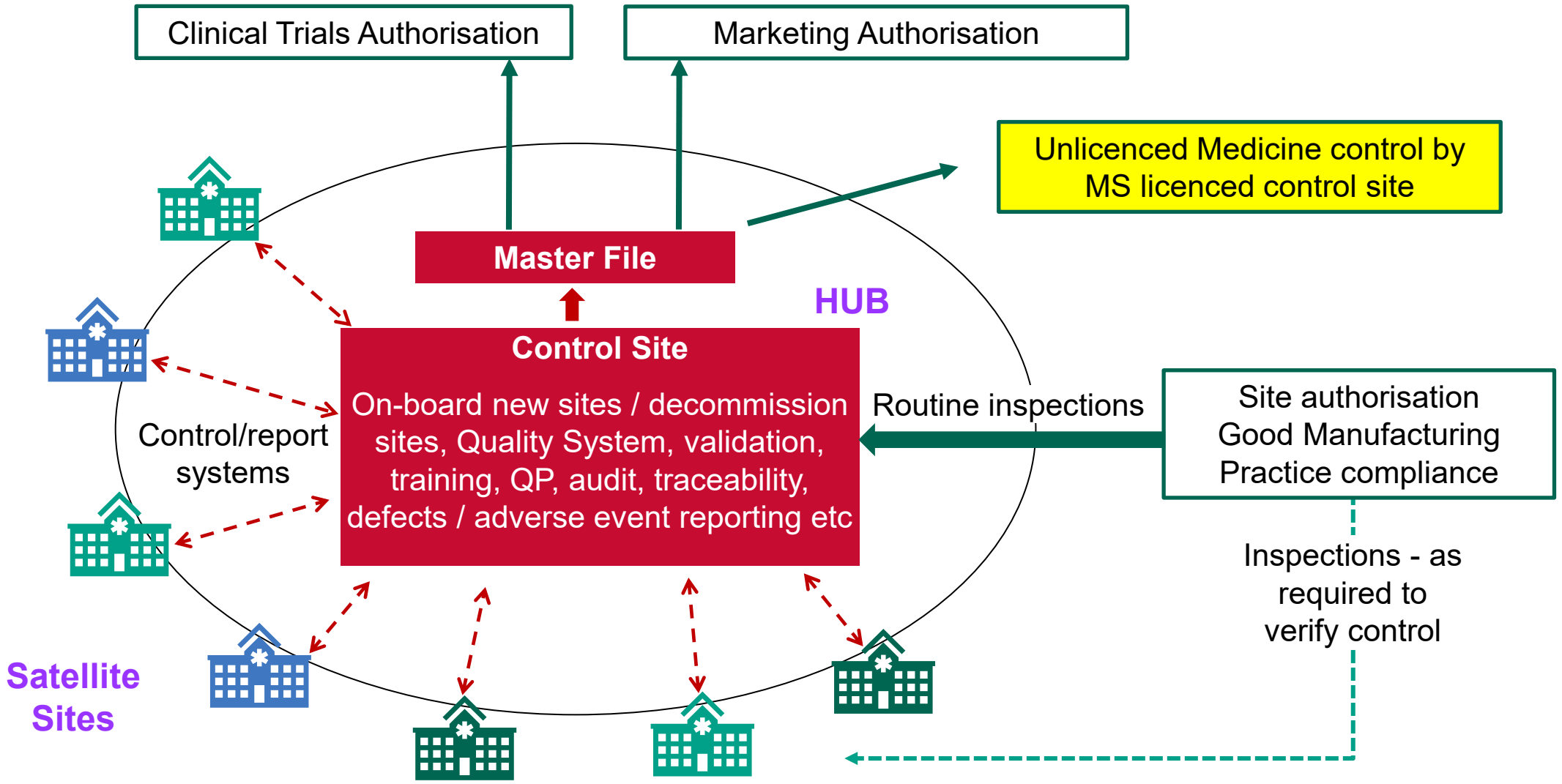
- The full range of pharmaceutical dosage forms: medical gasses, biological, biotech, blood, small molecule, advanced therapy medicinal products (ATMPs) etc
- All stages: Unlicenced / Specials medicines via MS licenced facilities, clinical trial and commercial products

A broadened spectrum of manufacturing and supply options



Common structure for all based on:
'**Hub**' (Control Site) and '**Satellite**' (POC/MM) model + **Master File**

Oversight – Control Site and Master File



Point of Care manufacture – key features

Products typically have short shelf life (range < 1 hour) of starting materials or finished products which results in:

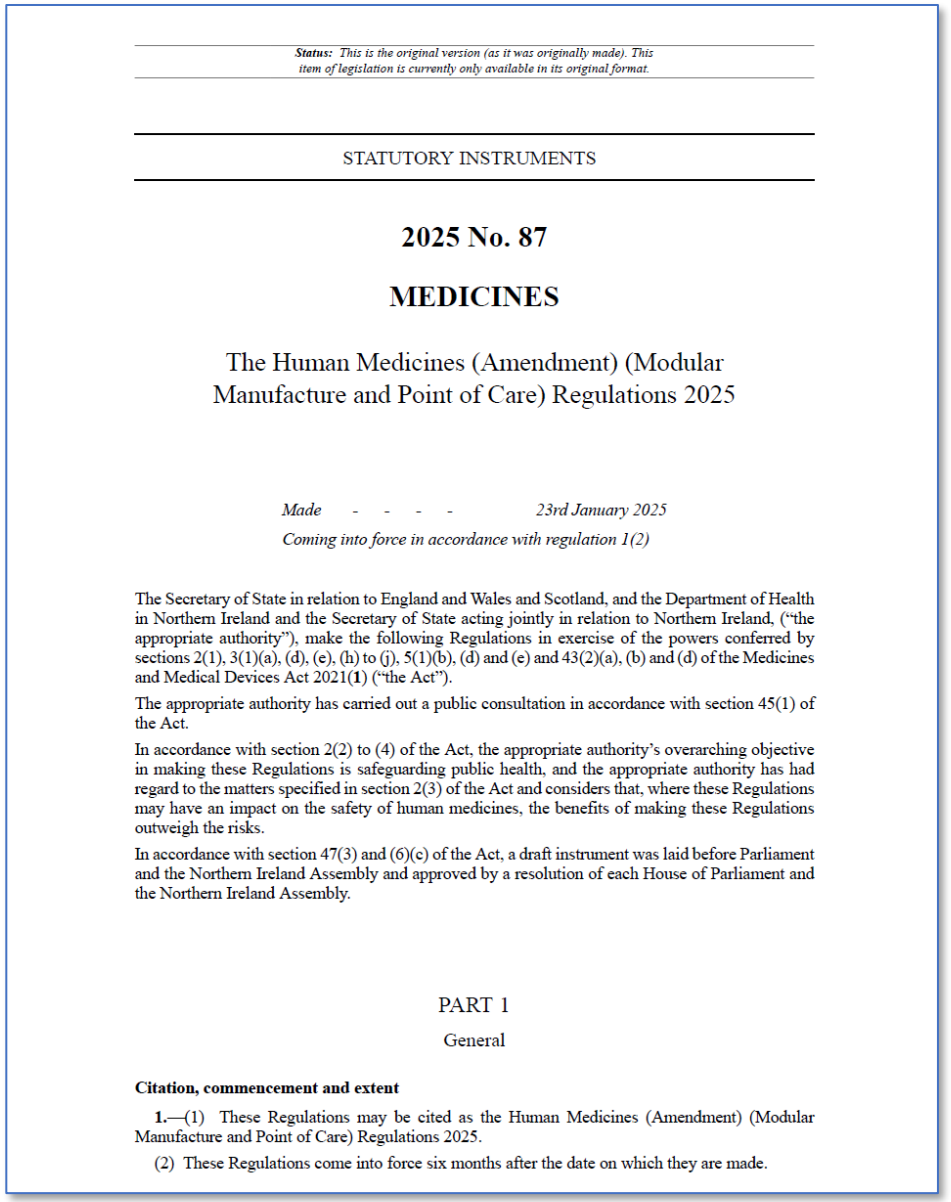
- Large number of manufacturing sites (scale out)
- Intermittent nature of manufacture
- Novel and wide range of manufacturing locations

Justify and convince the Regulatory Authority that the product "*can only be manufactured*" at or near the place where the product is to be used or administered

Basically – very close to the Patient!

Legislation

- The Human Medicines (Amendment) (Modular Manufacture and Point of Care) Regulations was signed into law as SI 2025/087 on 23 January 2025
- This SI amends the Human Medicines Regulations 2012 (HMR) and the Medicines for Human Use (Clinical Trials) Regulations 2004 (CTs).
- The SI came into effect on 23 July 2025
- This time was used for the development of technical and process guidance documents and a new DM Hub



Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

STATUTORY INSTRUMENTS

2025 No. 87

MEDICINES

The Human Medicines (Amendment) (Modular Manufacture and Point of Care) Regulations 2025

Made - - - - 23rd January 2025

Coming into force in accordance with regulation 1(2)

The Secretary of State in relation to England and Wales and Scotland, and the Department of Health in Northern Ireland and the Secretary of State acting jointly in relation to Northern Ireland, ("the appropriate authority"), make the following Regulations in exercise of the powers conferred by sections 2(1), 3(1)(a), (d), (e), (h) to (j), 5(1)(b), (d) and (e) and 43(2)(a), (b) and (d) of the Medicines and Medical Devices Act 2021(**1**) ("the Act").

The appropriate authority has carried out a public consultation in accordance with section 45(1) of the Act.

In accordance with section 2(2) to (4) of the Act, the appropriate authority's overarching objective in making these Regulations is safeguarding public health, and the appropriate authority has had regard to the matters specified in section 2(3) of the Act and considers that, where these Regulations may have an impact on the safety of human medicines, the benefits of making these Regulations outweigh the risks.

In accordance with section 47(3) and (6)(c) of the Act, a draft instrument was laid before Parliament and the Northern Ireland Assembly and approved by a resolution of each House of Parliament and the Northern Ireland Assembly.

PART 1

General

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Human Medicines (Amendment) (Modular Manufacture and Point of Care) Regulations 2025.

(2) These Regulations come into force six months after the date on which they are made.

The Designation process

- The Designation process is designed to be quick and to provide certainty for subsequent investment.
- Apply with:
  - Justification as to why the proposed product meets the legal test for Point of Care
  - Product background
  - Payment of a fee based on those for Scientific Advice where applicable
    - https://www.gov.uk/..../mhra-fees/payment-easements-and-waivers-for-small-and-medium-companies
- A designation decision will be provided by the MHRA:
  - within 60 days if no additional information and/or a meeting is required
  - within 90 days should additional information and/or a meeting be required
- The MHRA will not publish information about positive or negative DM designations.

The Decentralised Manufacture Master File (DMMF)

- Contains **Process** and **Product** aspects …
  - A template DMMF has been created to provide guidance on the information to include.
- The DMMF relates to a single DM medicinal product only and should not be generic or general in nature.
- DMMFs must be maintained and kept up to date, as a key Process and Product control document.
- Annual reporting of updates and changes to the DMMF is required.

GMP Manufacturing Licence and Quality System requirements

- Manufacturing licence holders will need to apply for the designation of Modular Manufacturing and/or Point of Care activities.
  - This will by product dosage form and will need to list each POC and / or MM type
  - The application will need to be accompanied by an applicable DMMF
- Licence holders will need Quality Systems and DM Master File processes in place to manage the approach for Decentralised processes, such as:
  - The approach to supervising and controlling operations at a ‘Satellite’ sites
  - Management of product release at ‘Satellite’ site, ensuring that manufacture or assembly is under appropriate control so that the medicinal product consistently satisfies the requirements in the Master File when manufactured at that ‘Satellite’ site
  - Oversight of training, equipment and facility controls

➢ See details in the GMP guidance document via the DM Hub page.

Institutional readiness

- Progress and adoption of innovation typically described and understood in terms of technical and regulatory readiness
- Adoption of disruptive innovation requires receptive organisations i.e. Institutional readiness
- Organisations must be aware of the changes and may need to make significant changes to processes, skills, culture, structures, operating / business models

How can “on site” manufacture of POC products be supported at NHS facilities?

- Via Traditional Pharmacy, Aseptic Services, Technical Services divisions?
- Via staff on the wards, next to theaters or even at the patients' homes?
- How can you train staff and ensure consistent processes in line with DMMF per product?
- Will it be NHS staff or can you support a central team coming to your site to manufacture?

How will the NHS sites interact with Control Sites, Sponsors for Clinical trials, or Marketing Authorisation holders for POC products that are rolled out?

Summary

There are three pillars to the successful adoption and implementation of this framework:

- Regulatory readiness – legislation, technical and procedural guidance documents ✓
- Technical readiness – products and processes ??
- Institutional readiness – in the organisation involved in this work ????

Interested parties for POC products and Control site oversight should:

- Assess the legislation, read the published technical and procedural guidance documents
- Put appropriate controls in place to support POC applications and product for MS licenced sites
- Engage early with MHRA:
  - During the DM development: e.g. Innovation Accelerator, Designation application, Scientific Advice

Interested parties for carrying out POC processes should:

- Consider partnership with a Control site
- Consider organisational need to support robust localised manufacturing

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