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# Introducing Gene Therapy Trials into an NHS Trust

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## Why?

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- Our Trust is highly research active with a number of specialist hospitals.
- Our NIHR Manchester Clinical Research Facility were being asked about their capacity to conduct Gene Therapy trials.
- Our clinicians are seeing them as a viable treatment option where none currently exist.
  - Rare genetic conditions (Eye)
  - Stem cell therapies
  - Haemophilias

## Understanding the requirements

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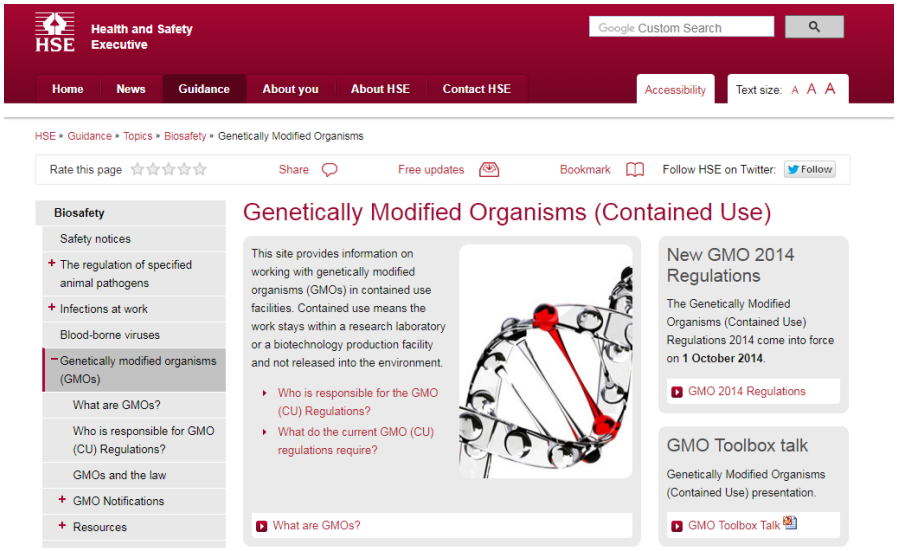


## Understanding the requirements

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**Regulations, Guidance and sample documents**

- Genetically Modified Organisms (Contained Use) Regulations 2014 and Deliberate release regulations.
- The SACGM Compendium of guidance part 6: Guidance on the use of genetically modified microorganisms in a clinical setting.
- Terms of reference for the University of Manchester Genetic Modification Safety Committee were obtained.
- Sample Risk Assessments were obtained from more experienced Trusts.

## Understanding the requirements

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**People**

- A meeting was held with The Christie Hospital's Quality lead who acts as their Biological Safety Officer and advice sought on systems.
- A meeting was held with the University of Manchester Biological Safety Officer to provide comparison.
- Teleconference with UCL personnel, who were sponsoring one of the proposed trials.

## What did we need to do?

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- Check Register (Genetically Modified Organisms Public Register Report)
- Contact HSE (responsible authority)
- Set up a Genetic Modification Safety Committee (GMSC)
- Obtain Trust Board support
- Identify stakeholders in conducting GT trials

## Competent Authorities

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- Who is responsible for the regulations varies between the devolved nations
- Check below to see the competent authority for you.

http://www.hse.gov.uk/biosafety/gmo/whos-responsible.htm

- For England the Health and Safety Executive (HSE) and the Secretary of State for the Department for Environment, Food and Rural Affairs (DEFRA) act jointly.

## Registration

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- Registered updated details with HSE
  - Contact,
  - Premises within Trust and
  - New GMSC arrangements
- Under contained use regulations
  - Class 1 trials this is sufficient
  - Class 2 trials and above, notification to HSE

## GMSC set-up

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- Identified members
- Identify staff with relevant expertise
- How would the decision be made?
  - Risk assessment form

## GMSC

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- In our Trust we have a monthly Early Phase Safety Committee (EPSC) which assesses whether high-risk (Phase 1) trials can be safely conducted onsite.
- The EPSC contained most of the relevant staff members/expertise needed for the GMSC, to avoid duplication
  - Expanded the EPSC by adding a consultant clinical scientist (virology) as a GM advisor.
  - Added questions about GMO product pathways (receipt, storage, preparation, transportation and waste) to the risk assessment

## Strategic Support

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- Presented intention paper to Trust Research Governance Committee
  - Board level committee chaired by Medical Director
  - Agreed to initially limit GT trials accepted to containment class 1 and 2 whilst building expertise
  - Agreed to develop Trust Code of Practice for GT trials
- Paper discussed at Operational Management Group (Divisional Managers across Trust for Hospitals and Clinical Support Departments)
  - Assisted in engaging stakeholders across the Trust

## Code of Practice (CoP)

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- Two remits
  - How-to guide for research teams
  - Raise Awareness that GT trials are happening at the Trust
- Identified departments to feed into the CoP including: Occupational Health, Infection Control, Waste Management, Clinical Research Facility, Stem Cell Laboratory, Pharmacy, Laboratories, Radiology and Pathology.
- Met with key individuals
- Code of Practice published on Trust intranet

## Embedding into Trust

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- Training and awareness raising
- Widening the personnel in clinical departments with the expertise
- Reflecting on lessons learned from each trial

**Next steps…..**
New members on EPSC
Funding in place to increase expertise across Trust
Further funding for pharmacy requirements

## Lessons Learned

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- Time and effort
- Ask the sponsors!
- Important to get Board/senior management support because while some departments engage really well (waste management), others need pressure applied.
- Don’t assume paragraphs in a Code of Practice equate to practical departmental procedures.
- Engage ground level staff.
- Realise it is an ongoing process and you will learn with every trial.

## Summary

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