GMP Cellular Starting Material: Myth or Reality?

Expert briefing

Can Cellular Starting Materials be ‘GMP’?

ANTHONY NOLAN
Cell Therapy and Laboratory Services

Summary

The regulatory landscape around cellular starting materials and good manufacturing practice (GMP) is complex to navigate, especially when you are developing innovative advanced therapies and creating processes which haven't been tried or tested before.

Anthony Nolan has been at the forefront of clinical cell therapy provision for over 50 years. Our Cell Therapy and Laboratory Services make use of this expertise to bring an unrivalled service to developers navigating the regulatory landscape.

Unmodified cellular starting materials cannot be governed by GMP. Subsequent processing of cellular starting materials may require adherence to GMP guidelines and transitioning starting material from a supplier into a GMP-governed environment can feel challenging. Anthony Nolan’s Cell Therapy and Laboratory Services team can help you determine which regulations must be followed and guide you through your unique development process.

What is GMP?

In the UK or the EU, good manufacturing practice guidelines apply to any cellular materials that are being processed for medicinal purposes.

GMP is risk-based compliance in the UK governed by inspections carried out by the Medicines and Healthcare products Regulatory Agency (MHRA). It is the minimum standard that medicines manufacturers must meet in their production processes. Products must be of a consistent high quality, appropriate to their intended use, and meet the requirements of the marketing authorisation (MA) or product specification.

GMP guidelines do not apply to the collection of cellular starting materials as they have not undergone any processing which modifies or changes the cells. For the purposes of GMP, cryopreservation or transport are not considered cellular modifications in the UK. If required Anthony Nolan will use their Human Tissue Authority licence for these activities.

Although provision of cellular starting material does not have to adhere to GMP guidelines, any further processing or modification of the cells would be governed by the MHRA in the UK, or the EMA in the EU, and would have to follow GMP guidelines.

For many developers, cellular starting material will need to transfer directly into a GMP-governed environment once it is received. While cellular starting material provision does not fall under the GMP umbrella, there are still significant regulatory aspects to be aware of when sourcing your starting material.

Understanding the regulations that apply to cellular starting material will help build confidence that this transfer can happen effectively.

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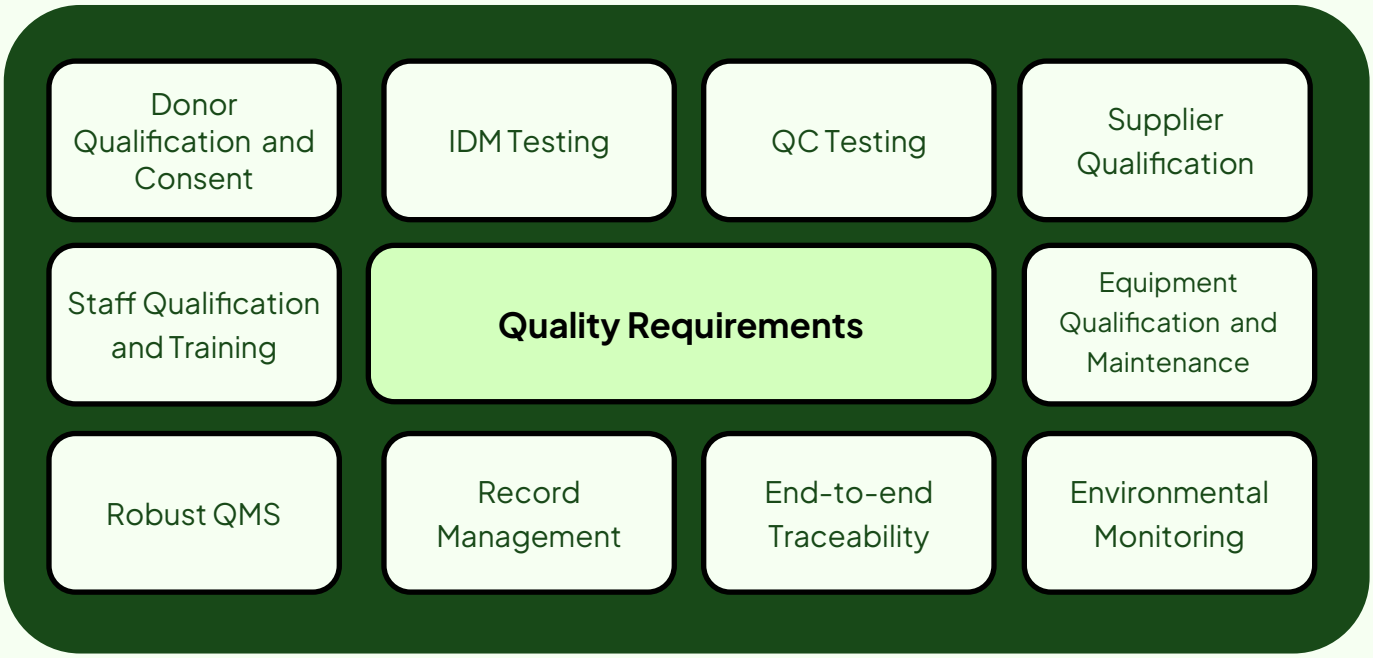
Regulations in the supply of cellular starting material

Various regulations must be adhered to for any provider of cellular starting material and are monitored by the Human Tissue Authority (HTA) in the UK.

The table below outlines key requirements for establishing starting material quality:



Although not subject to GMP guidance for starting material provision, many of these requirements can also be seen within GMP guidance. At Anthony Nolan's Cell Therapy and Laboratory Services, we have extensive experience in ensuring we meet these requirements and understand the overlaps. This puts us in a unique position to advise and work with you along the product development pathway.

Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations), the HTA licenses and inspects establishments that undertake the procurement, testing, processing, storage, distribution, import and export of tissues and cells for human application.

GMP commences on receipt of the raw starting materials from your supplier. To ensure you are able to meet GMP requirements, in the UK you need to be sure your supplier is meeting the HTA regulations in the supply of cellular starting material; this can be managed via supplier qualification processes which can include audits and supplier qualification assessment questionnaires.

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Key areas for compliance with Good Manufacturing Practices:

- Pharmaceutical quality system
- Personnel Premises and equipment
- Documentation
- Production
- Quality control
- Outsourced activities
- Complaints and product recall
- Self-inspection

More details can be found here

Need to decide how to approach regulatory requirements for your specific project?
Here are some questions to consider:

- Is my project clinical or non-clinical?
- Do I need to source processed cells (i.e. CD34+)?
- At what stage am I modifying my starting material?
- Is my UK supplier meeting HTA regulations in the provision of starting material?

Anthony Nolan's Cell Therapy and Laboratory Services team can help you answer these questions and determine the appropriate level of regulation you'll need to adhere to at each step of your product development.

The specific regulations may differ depending on your application (i.e. clinical / non-clinical) and processing methods.

About Anthony Nolan's Cell Therapy and Laboratory Services

Powered by Anthony Nolan's large donor register and 50 years' experience in the fields of haematopoietic cell therapies, our full-service capabilities provide solutions to get you from bench to bedside – including cell collection, genetic testing, sequencing services, cell processing, cryopreservation and advisory services. Our donor registry is accredited by the World Marrow Donor Association (WMDA) in the following categories:

- General organisation of Registry,
- Donor recruitment
- Donor characterisation
- Information technology
- Facilitation of search requests
- Second/subsequent donations
- Collection/processing/transporting stem cells
- Follow up of patient/donor
- Financial/legal liabilities

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About Anthony Nolan's Cell Therapy and Laboratory Services

Our mission is to accelerate your cell and gene therapy innovations to help more patients survive and thrive. Our end-to-end offering combines cellular starting materials with the expertise and services needed at each phase of the scale-up journey.

Anthony Nolan additionally holds a Human Tissue Authority license, allowing our registry in London, our Cell Collection Centre and Cell Therapy Centre in Nottingham and cord blood programme to carry out the following activities: procurement, testing, processing, storage, storage of relevant materials, distribution and/or import/export of tissues and/or cells intended for human application.

Our Cell Therapy Centre houses our research tissue bank which has National Ethical Approval and our cord blood programme has FACT-NetCord accreditation. Our Histocompatibility Laboratory is also accredited by the United Kingdom Accreditation Service and the European Federation for Immunogenetics.

About Salmah Mahmood Ahmed

Salmah is Director of Quality and Regulation at Anthony Nolan. She has worked with the organisation since 2012 developing Anthony Nolan's approach to quality which she now leads across register operations and donor provisions, the Cord Blood Programme, Anthony Nolan's Cell Collection Centre, and H&I Laboratories.

Salmah leads the organisation's licencing and accreditation, alongside inspections and audits. She engages with key regulatory bodies in the industry at a strategic level with a critical focus on donor safety.

Salmah has held various roles within the World Marrow Donor Association group on quality and regulation, and more recently she was chair and the driving force behind the formation of the Cell and Gene Therapy Committee. She is a leading voice in the global conversation on quality and regulation across registers around the world.

Salmah's background is in Biomedical Science, and she has a deep professional interest in Regulatory Affairs working towards an MSc in this field.

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