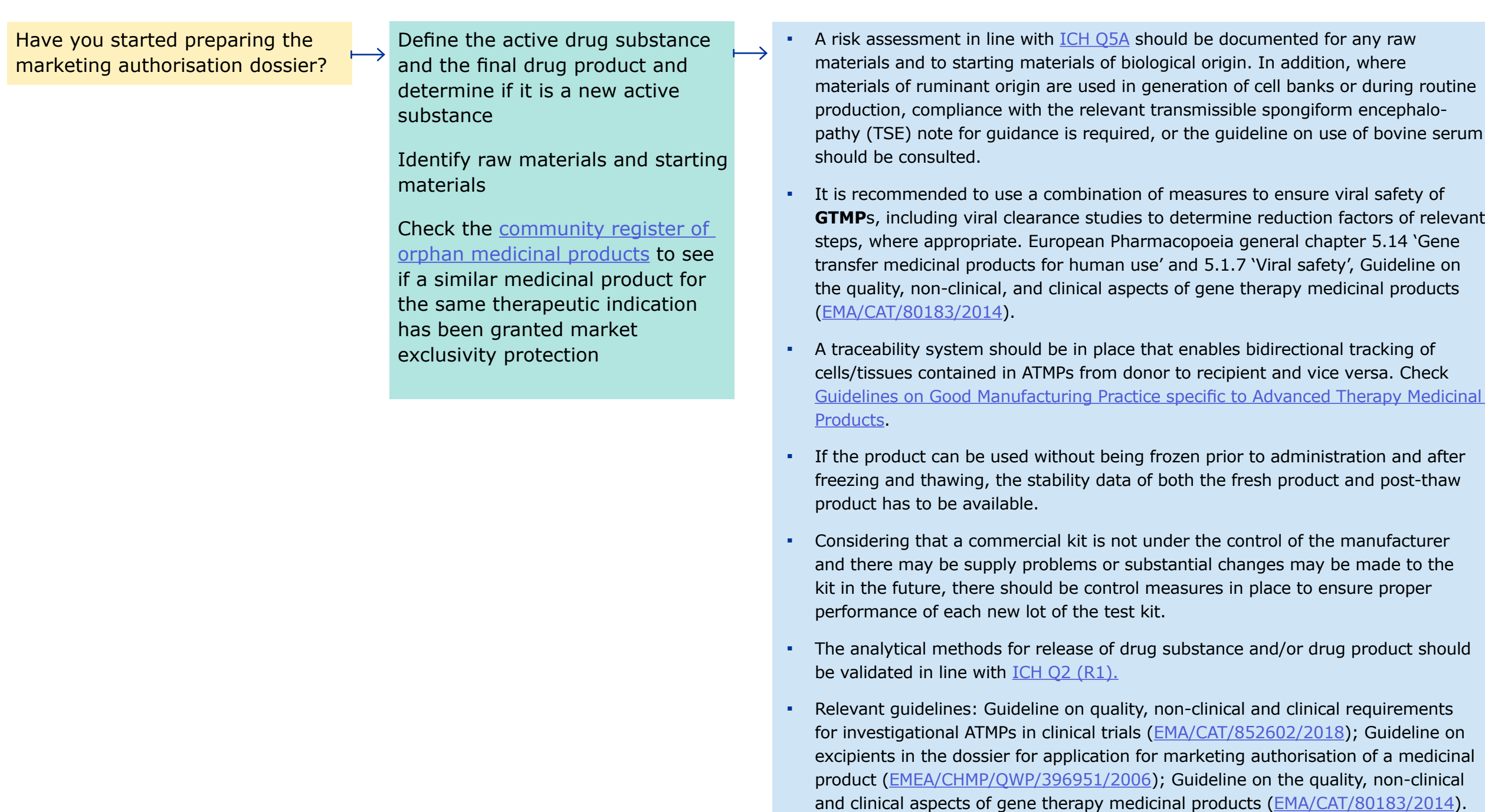
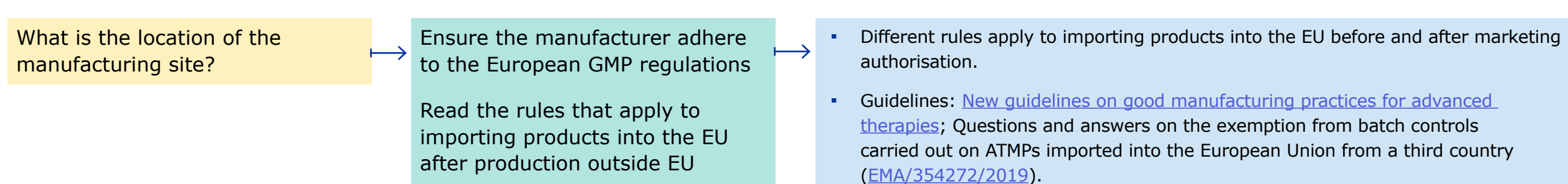
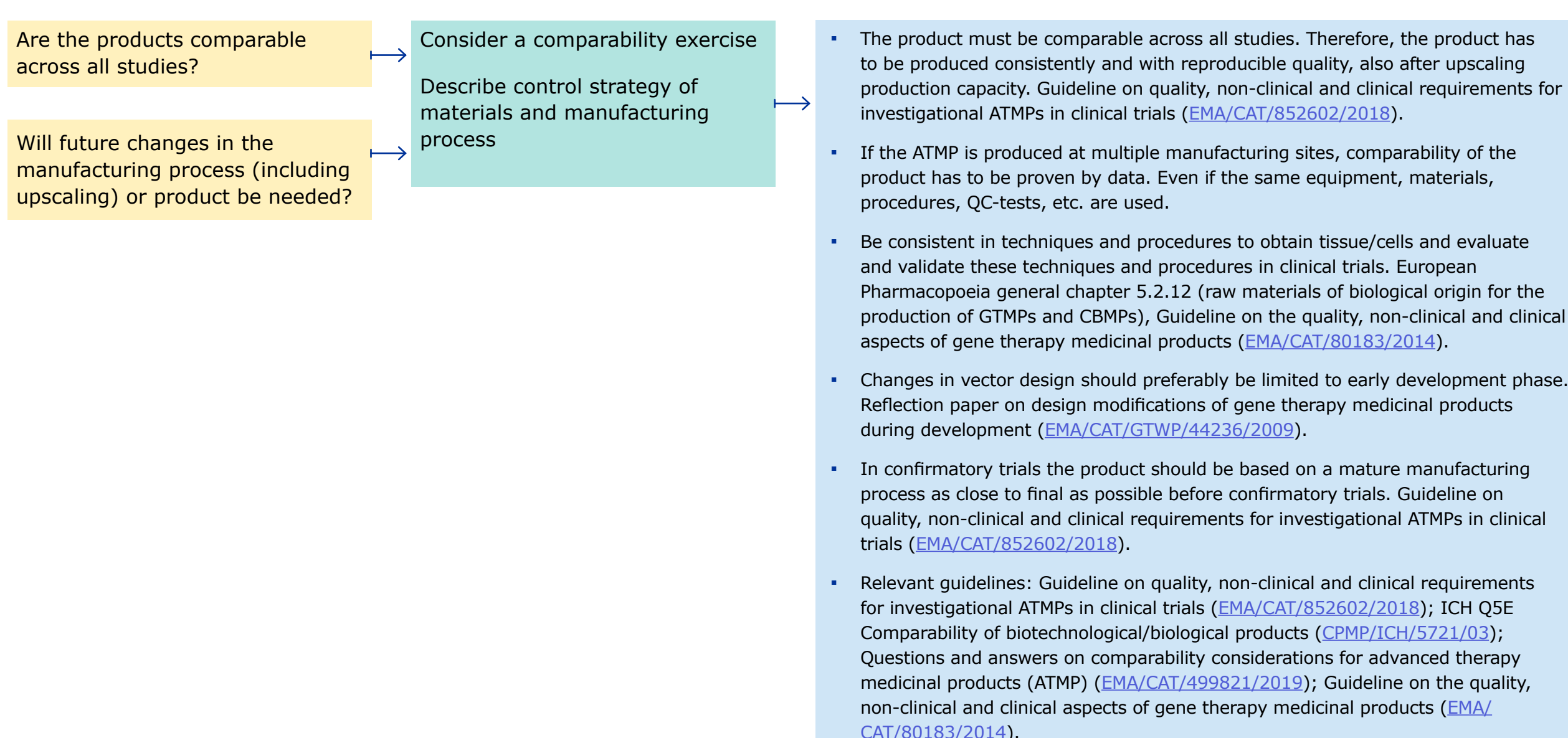
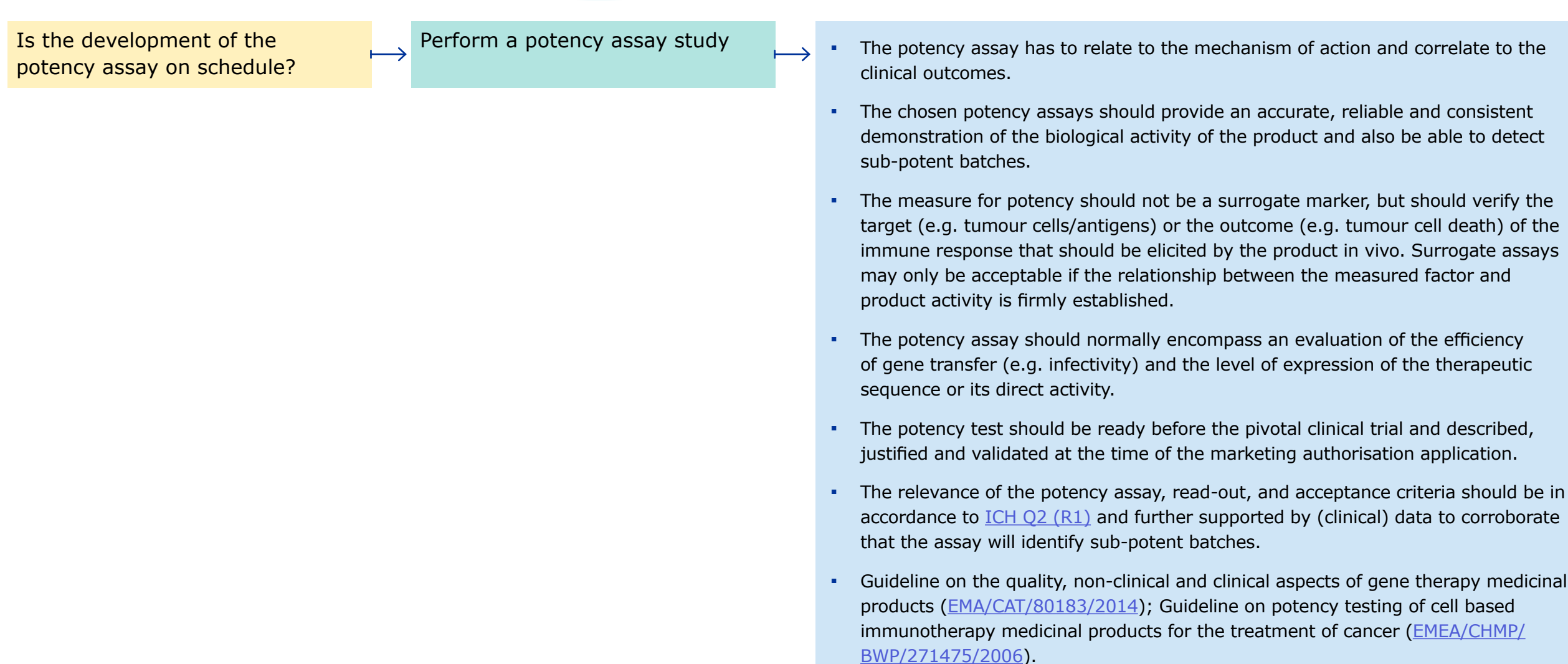
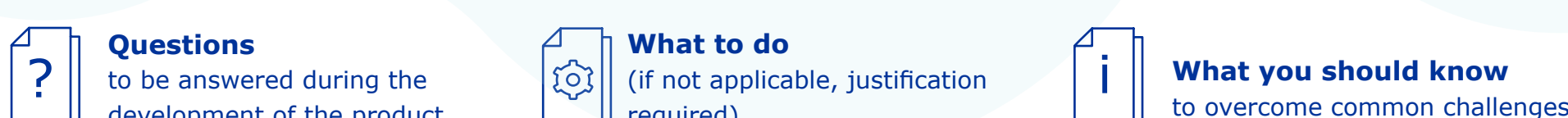


Quality

To help developers of gene therapy medicinal products (GTMPs) and cell-based medicinal products (CBMPs) navigate the most important quality-related regulatory requirements



What you should know

Additional information applicable to all the above objectives

- [Guidelines relevant for advanced therapy medicinal products](#)



Your checklist

- Develop and validate a potency assay
- Check the GMP regulations for importing products into the EU
- Map the development of the manufacturing process and ensure the products across all studies are comparable
- Explore what is needed in the authorisation dossier
- Define the active drug substance and final drug product
- Identify raw materials and starting materials
- Check the [Community register of orphan medicinal products](#) to see if a similar medicinal product for the same therapeutic indication has been granted market exclusivity protection
- Develop a traceability system that enables bidirectional tracking of cells/tissues contained in ATMPs



Regulatory support

ATMP certification: this procedure aims to identify any potential issues of quality and non-clinical data. For more information see [Certification procedures for micro-, small- and medium-sized enterprises \(SMEs\)](#)

ATMP classification: it is to determine if the product meets the scientific criteria ATMPs and consequently to clarify the applicable regulatory framework, development path and scientific/regulatory guidance to be followed. For more information see [Advance therapy classification](#)

ITF: the innovation task force (ITF) is a multidisciplinary group that includes scientific, regulatory and legal competences. It was set up to provide a forum for early dialogue with applicants on innovative aspects in medicines development. For more information see [Innovation in medicines](#)

Orphan designation: designated for rare disease can termed orphan medicines. Sponsors of designated orphan medicines can benefit from incentives. For more information see [Orphan designation: Overview](#)

Orphan similarity: check the Community register of orphan medicinal products to see if a similar medicinal product for the same therapeutic indication has been granted market exclusivity protection. For more information see [Applying for marketing authorisation: orphan medicines](#)

PRIME status: it allows support for the development of medicines that target an unmet medical need. For more information see [PRIME: priority medicines](#)

Scientific advice and protocol assistance: developers can be advised on the most appropriate way to generate robust evidence on a medicine's benefits and risks. During the non-clinical development phase and prior to the start of the clinical phase. For more information see [Scientific advice and protocol assistance](#)

SME status: the micro, small and medium-sized enterprise (SME) status can be used to benefit from regulatory and administrative assistance, and fee incentives. It is recommended to register as soon as possible. For more information see [Supporting SMEs](#)