NATIONAL BIOPRODUCTS INSTITUTE NPC

PLASMA FOR FRACTIONATION:

Regulatory submissions for the approval of plasma suppliers

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NBI is a "not for profit" company committed to providing safe, cost effective, quality medicinal products

Medicines Control Council

- Applies standards laid down by Medicines and Related Substances Act (101 of 1965)
- Regulates the performance of clinical trials
- Registration of medicines and medical devices
- Ensures that all medicines comply with necessary requirements for safety, quality and efficacy
- Operates through external experts who are members of the council

Product Dossiers

- A document that contains the technical data proving the quality efficacy and safety properties suitable for the intended use
- Covers administrative, quality, nonclinical and clinical aspects related to the pharmaceutical product
- Content and format of the dossier must follow rules and guidelines as defined by the Regulatory Authority

The goal of the Product Dossiers

- The pharmaceutical product is safe and effective in its proposed use when used as directed

- The products proposed labelling is appropriate

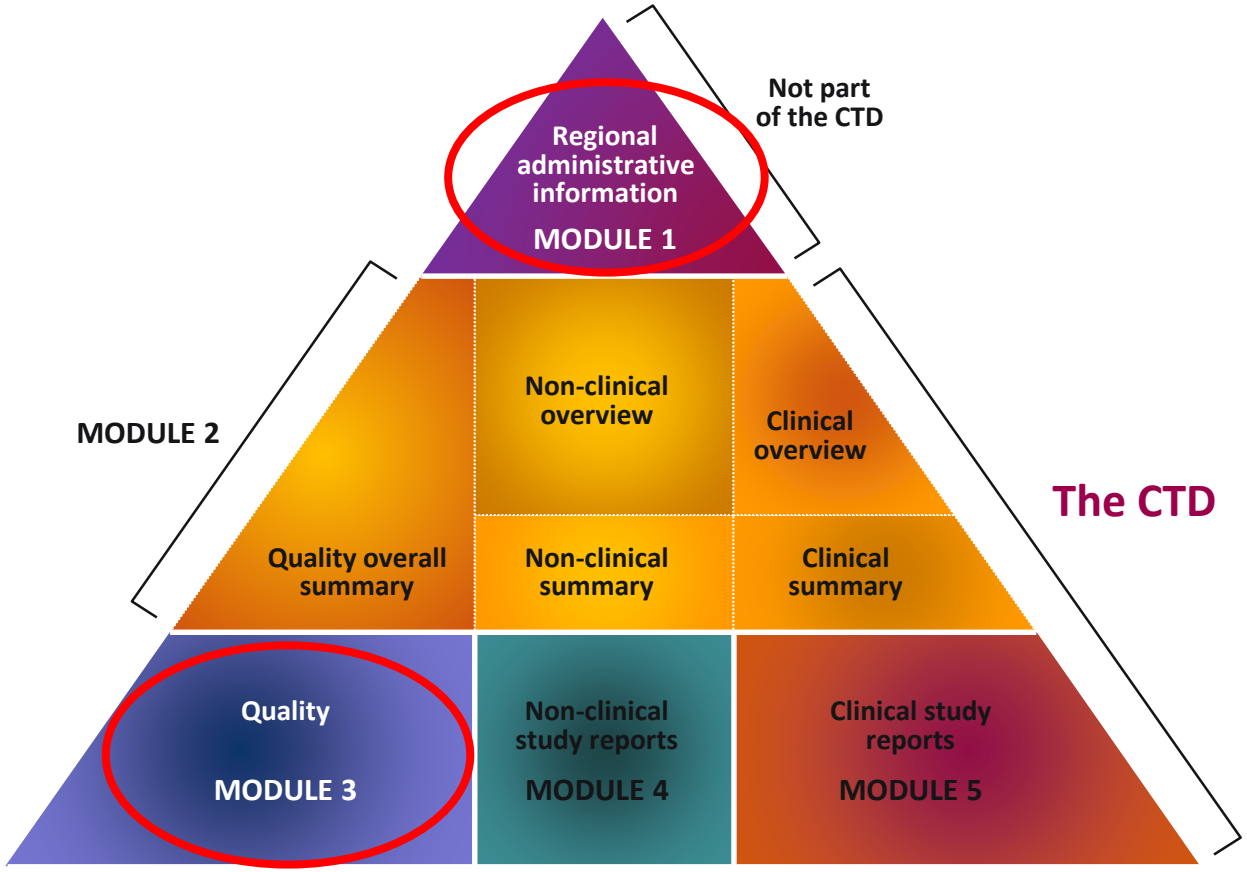
- The methods used in Manufacturing of the pharmaceutical product and the controls used to maintain the products quality is adequate to preserve its identity, strength, quality and purity

Addition of a plasma supplier

CTD

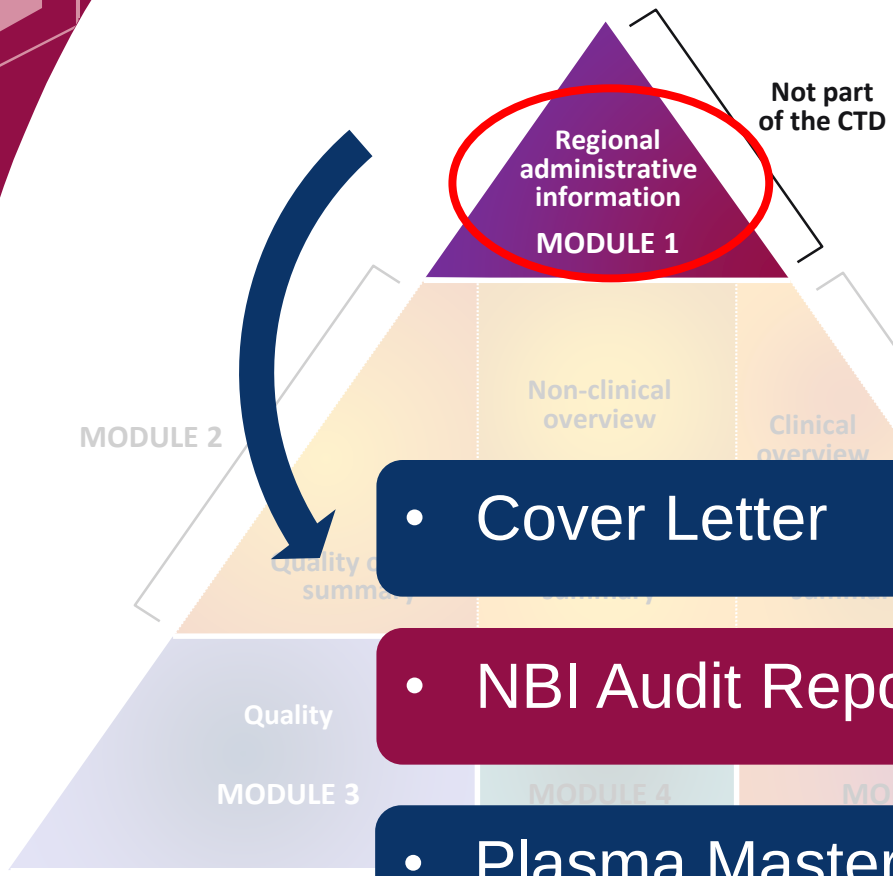
Involves an application in ***Common Technical Document*** (CTD) format for submission to the MCC that will cover all products that will be manufactured from that plasma supplier

Common Technical Document



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions

Module 1 information



- Cover Letter
- NBI Audit Report
- Plasma Master File

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Plasma Master File

Plasma Origin

Plasma Quality and Safety

Epidemiology data/ PMF certificate

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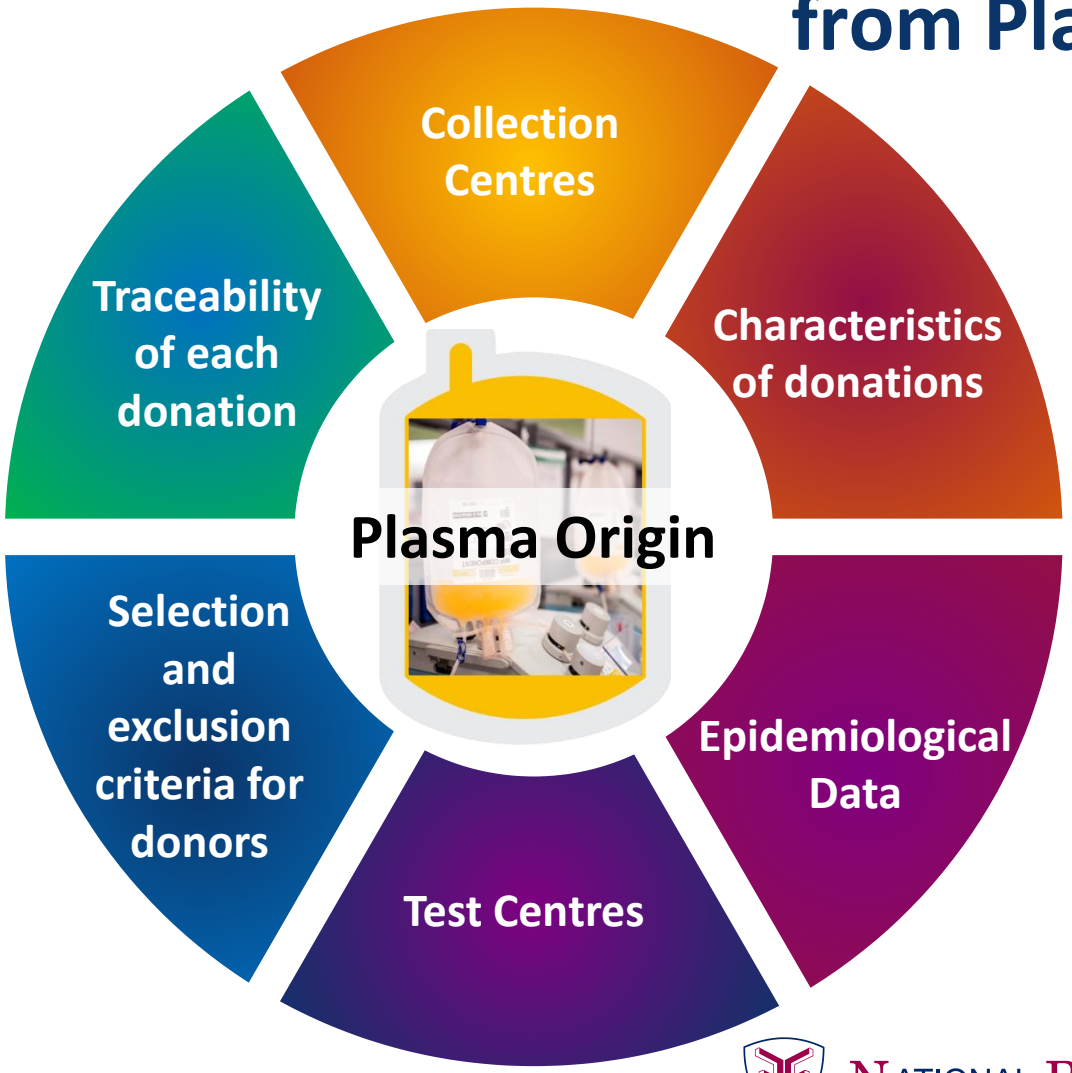
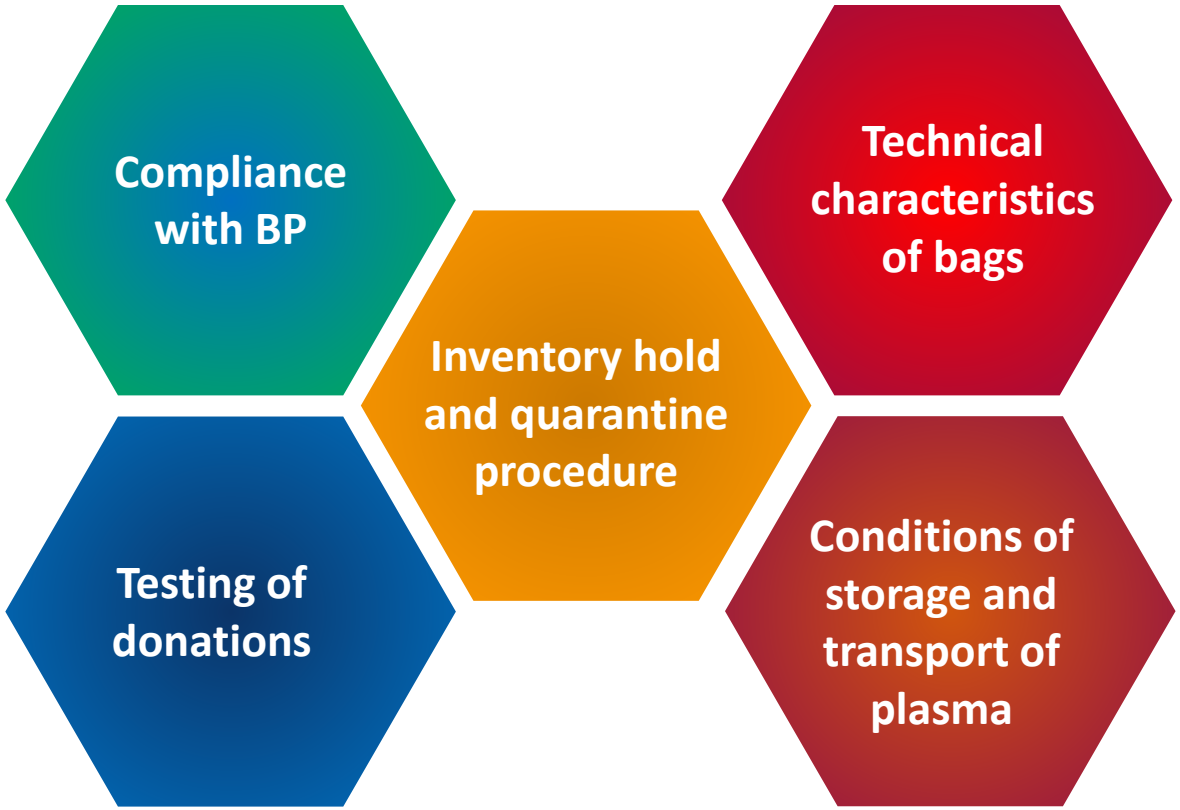
Plasma Origin Information from Plasma supplier

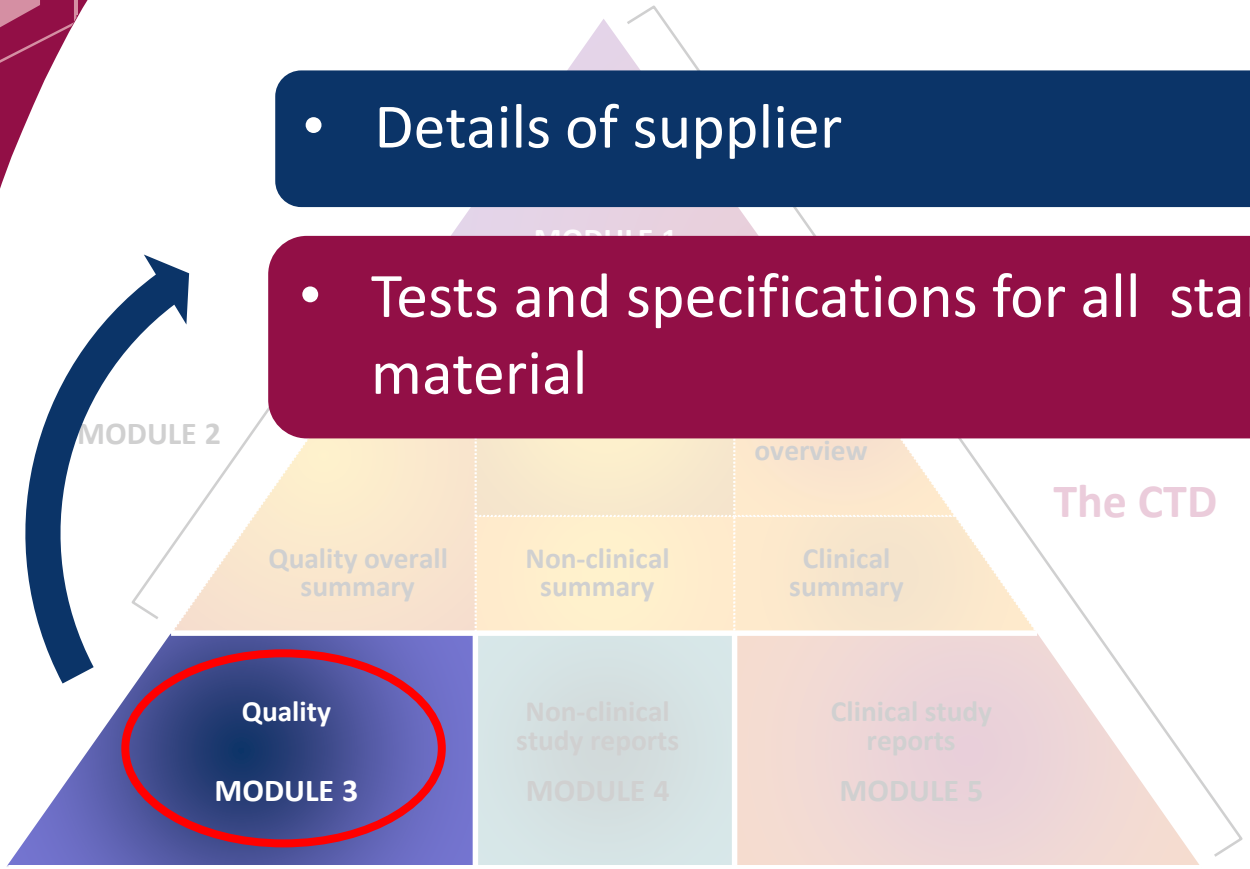


Plasma Quality and Safety Information from Plasma supplier



Module 3 information

- Details of supplier
- Tests and specifications for all starting material



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Regulatory Evaluation Process

- Involves review by multidisciplinary experts
- May result in recommendations and further request for information or documentation
- Time frames for approval varies
  - ✓ Generally a few months
- Plasma can only be procured and used once approval is received- Type C amendment

Thank You

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