Patient Centric Specifications: How can they be established and maintained, or if justified amended

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An appropriately supported and justified patient centric specification (PCS) or enhanced specification can provide broader access to biologics of high quality. Whereas, an overly stringent specification, or the tightening of a specification based on improvements in manufacturing capability or assay performance in the context of a robust PCS, may lead to the reduced product availability, as well as potentially increase the cost of those drugs.

Questions

- What are manufacturer's experiences when proposing a "robust" PCS in a commercial license application, with acceptance criteria beyond manufacturing experience?
- How can manufacturer defend a proposed enhanced/patient centric specification at time of registration?

- What are successful strategies to expand a specification post-authorization?
- Post-authorization and in the absence of safety or manufacturing issues, is there scientific justification for tightening a specification based on increased manufacturing consistency or assay performance?