Meeting the challenge of patient-centric specifications

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Specifications are essential for assuring that marketed products will perform comparably to that which was tested in the clinic. Where information to support a link between specifications and clinical outcomes is sparse, there is a tendency to choose specifications based on product consistency. Thus, the key challenge is to obtain enough data to support this link to clinical outcomes, both for safety and efficacy specifications. Creative use of all sources of information related to CMC, the quality system, along with strategically designed clinical studies and post-licensure studies can facilitate creation and maintenance of this link.