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Table 12-1. Regulatory Key Questions During Development Key
Area Considerations for EU Development Program Intended Use

- What are the proposed indications for use?
- What is the target patient population(s) and/or anatomical site(s)?

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Ruthanne Vendy, RAC, a Senior Principal Specialist at R&Q, was selected to be a contributing author to the Regulatory Affairs Professionals Society's (RAPS) Fundamentals of EU Regulatory Affairs, Ninth Edition, which was recently updated to cover the

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upcoming implementation of the European Union ' s new Medical Devices Regulation (EU MDR) and In Vitro Diagnostics Regulation (EU IVDR), and the subsequent impact for manufacturers, Notified Bodies, competent authorities, and other stakeholders.

R&Q's Ruthanne Vendy Contributes to RAPS Fundamentals of ...
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and Barry A. Berger, JD, MBA

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