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variations Marketing Authorisation
in EU | European Medicines
Agency (EMA) | MRP, DCP, CP
& National Procedure

1. Overview of the EMA and the
centralised procedure What Is The
Regulatory Startup Process In A
Clinical Research Study? e-

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Learning: Introduction to EU

Marketing Authorisation Module

~~01 – Setting the scene:~~

~~introduction to the EU regulatory
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Affairs: Many Hats to Wear ~~The~~

~~Founding of the EU~~ What

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Regulatory Affairs Medical
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products meet stringent safety
requirements.

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Agenda Download | Fundamentals
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Regulatory Affairs Professionals
Society 137 Regulatory Strategy
Table 12-1. Regulatory Key
Questions During Development
Key Area Considerations for EU
Development Program Intended

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

Chapter 12 Regulatory Strategy - RAPS

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Chapter 1 EMA and Other EU
Regulatory Bodies 1

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Ruthanne Vendy, RAC, a Senior
Principal Specialist at R&Q, was
selected to be a contributing

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author to the Regulatory Affairs
Professionals Society 's (RAPS)
Fundamentals of EU Regulatory
Affairs, Ninth Edition, which was
recently updated to cover the
upcoming implementation of the
European Union 's new Medical
Devices Regulation (EU MDR) and

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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

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Chapter 1 FDA and Related
Regulatory Agencies.....1 By
Mitchell S. Berger, MPH, JD, RAC
and Barry A. Berger, JD, MBA

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