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(EMA) | MRP, DCP,
CP \u0026amp; National
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EMA and the

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Centralised

procedure What Is

The Regulatory

Startup Process In

A Clinical Research

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the scene:

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network

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System

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4.2 Regulatory
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Medical Devices

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Crash, and
Response

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~~ACTUAL Career!~~

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Devices) DOSSIER
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,REGULATORY

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The pharmaceutical and biotech industries are the most regulated in the world due to the nature of the product. Patient safety is central to all decisions, processes,

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procedures,
guidance and
regulations.

Regulatory agencies
such as the MHRA
and EMA are in
place to ensure new
and existing
products meet
stringent safety
requirements.

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indicated by

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or “ c ” to the page
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Regulatory Strategy
Table 12-1.

Regulatory Key

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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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regulatory function
is vital in making
safe and effective
healthcare products
available worldwide.
Individuals who
ensure regulatory
compliance and
prepare
submissions, as
well as those whose

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main job function is
clinical affairs or
quality assurance
are all considered
regulatory
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Ruthanne Vendy,
RAC, a Senior
Principal Specialist
at R&Q, was
selected to be a
contributing author
to the Regulatory
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ciety ' s (RAPS)

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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 In Vitro
Diagnostics
Regulation (EU

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(IVDR), and the subsequent impact for manufacturers, Notified Bodies, competent authorities, and other stakeholders.

R&Q's Ruthanne
Vendy Contributes
to RAPS
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