Medical Devices Regulation
Elekta Solutions

Anders Skoglund
SVP Regulatory Affairs & Quality

Louise Wachtmeister
VP Regulatory Affairs & Quality

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“assure predictable & sustainable market access”

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Elektas transition to MDR

MDD Certificates
Each Legal Manufacturer have their own ISO, MDSAP and MDD certificates

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Notified Bodies

Each Legal Manufacturer have their own Notified Body

7

Products / Technical Files
An industry history of approvals on low level to simplify & speed up submissions

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One Legal Manufacturer
Placing all products on all markets reducing certification costs, speed to market and complexity.

One Notified Body
Simplifying complexity with interpretations and overhead to the QMS.

System Level Approvals
Reducing number of submissions, time to market and costs. Target less than 20.

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Notified Body

Evaluate Scope
Scope evaluation under MDD

Initial meetings
To evaluate interest and product coverage.

Agreement
Sign agreement as early as possible to assure NB availablity

bsi.

One Notified Body
Covering all areas of Elekta, all products globally

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Elekta EU Sales HQ
Located in UK

Elekta Authorized Representative
Located in UK

MDD Notified Bodies
Several UK based and not supporting transition to Europe

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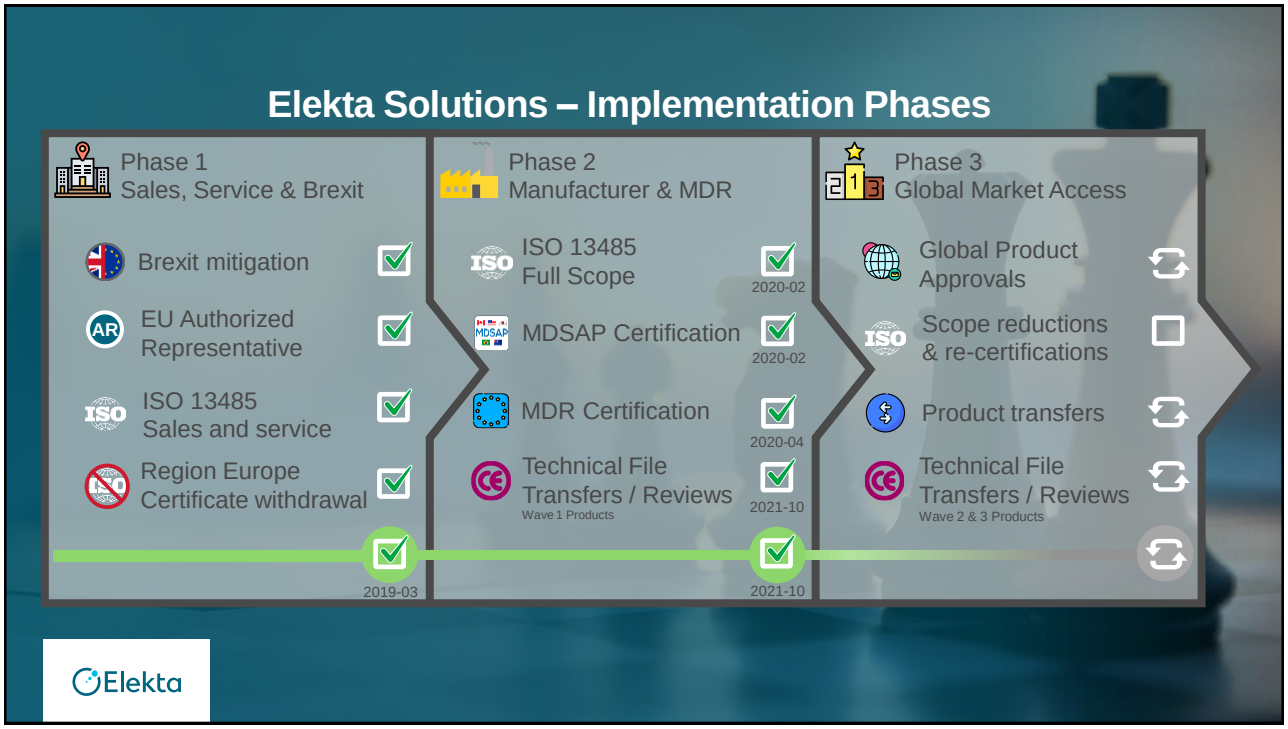
Elekta Solutions – Implementation Phases
Phase 1
Sales, Service & Brexit
Brexit mitigation
EU Authorized Representative
ISO 13485 Sales and service
Region Europe Certificate withdrawal
2019-03
Phase 2
Manufacturer & MDR
ISO 13485 Full Scope
2020-02
MDSAP Certification
2020-02
MDR Certification
2020-04
Technical File Transfers / Reviews
Wave 1 Products
2021-10
2021-10
Phase 3
Global Market Access
Global Product Approvals
Scope reductions & re-certifications
Product transfers
Technical File Transfers / Reviews
Wave 2 & 3 Products
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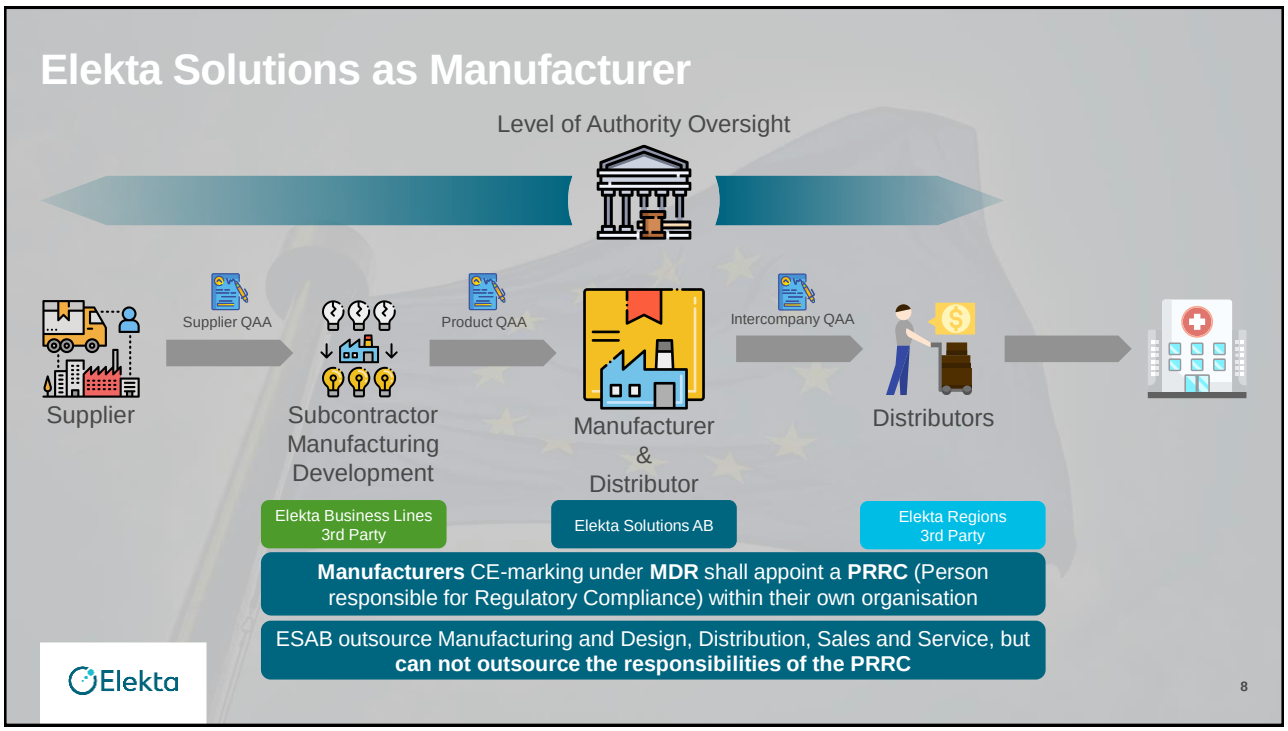
Elekta Solutions as Manufacturer
Level of Authority Oversight
Supplier
Supplier QAA
Subcontractor Manufacturing Development
Product QAA
Manufacturer & Distributor
Intercompany QAA
Distributors
Elekta Business Lines 3rd Party
Elekta Solutions AB
Elekta Regions 3rd Party
Manufacturers CE-marking under MDR shall appoint a PRRC (Person responsible for Regulatory Compliance) within their own organisation
ESAB outsource Manufacturing and Design, Distribution, Sales and Service, but can not outsource the responsibilities of the PRRC
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Notified Body Review Process

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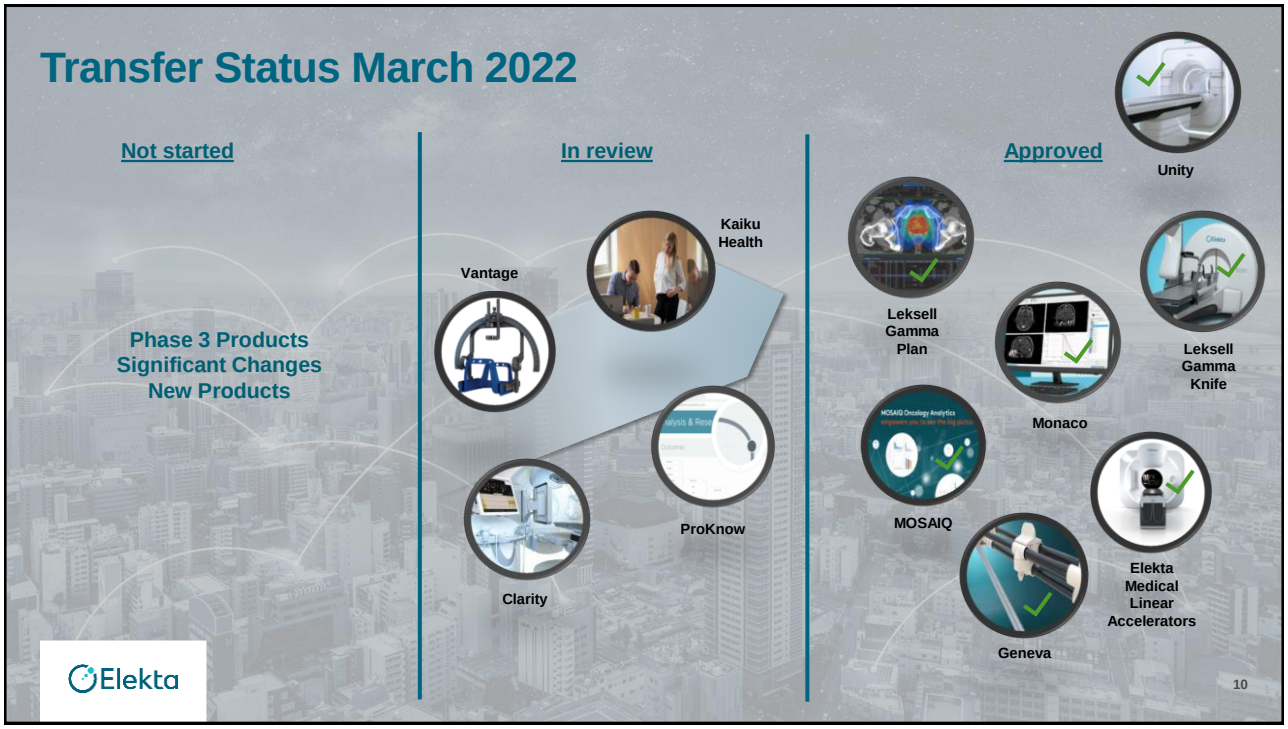
Transfer Status March 2022



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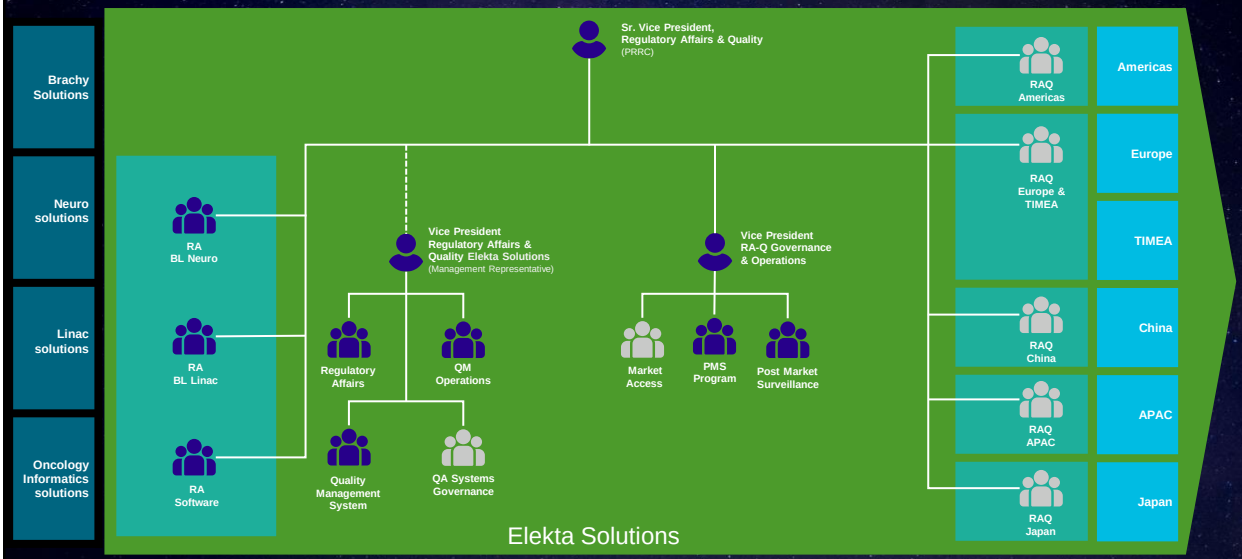

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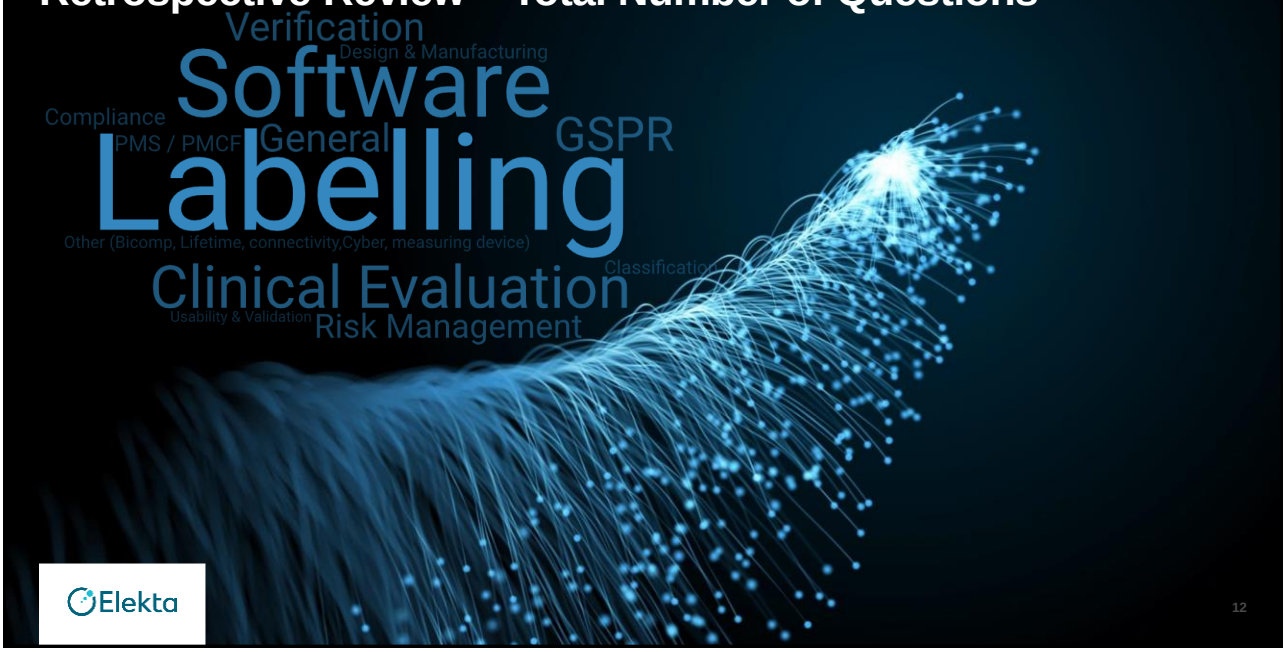
Retrospective Review – Total Number of Questions



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Retrospective Review – Remaining after 3 set of questions

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