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New Product Introduction (NPI) and Packaging Validation Considerations

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Project Services

Journey to Product Launch Success with Almac

1 Framework

Regulatory framework & pathway for global supply

2 Support

EU requirements for Qualified Person (QP) & Responsible Person (RP)

3 Development to commercial

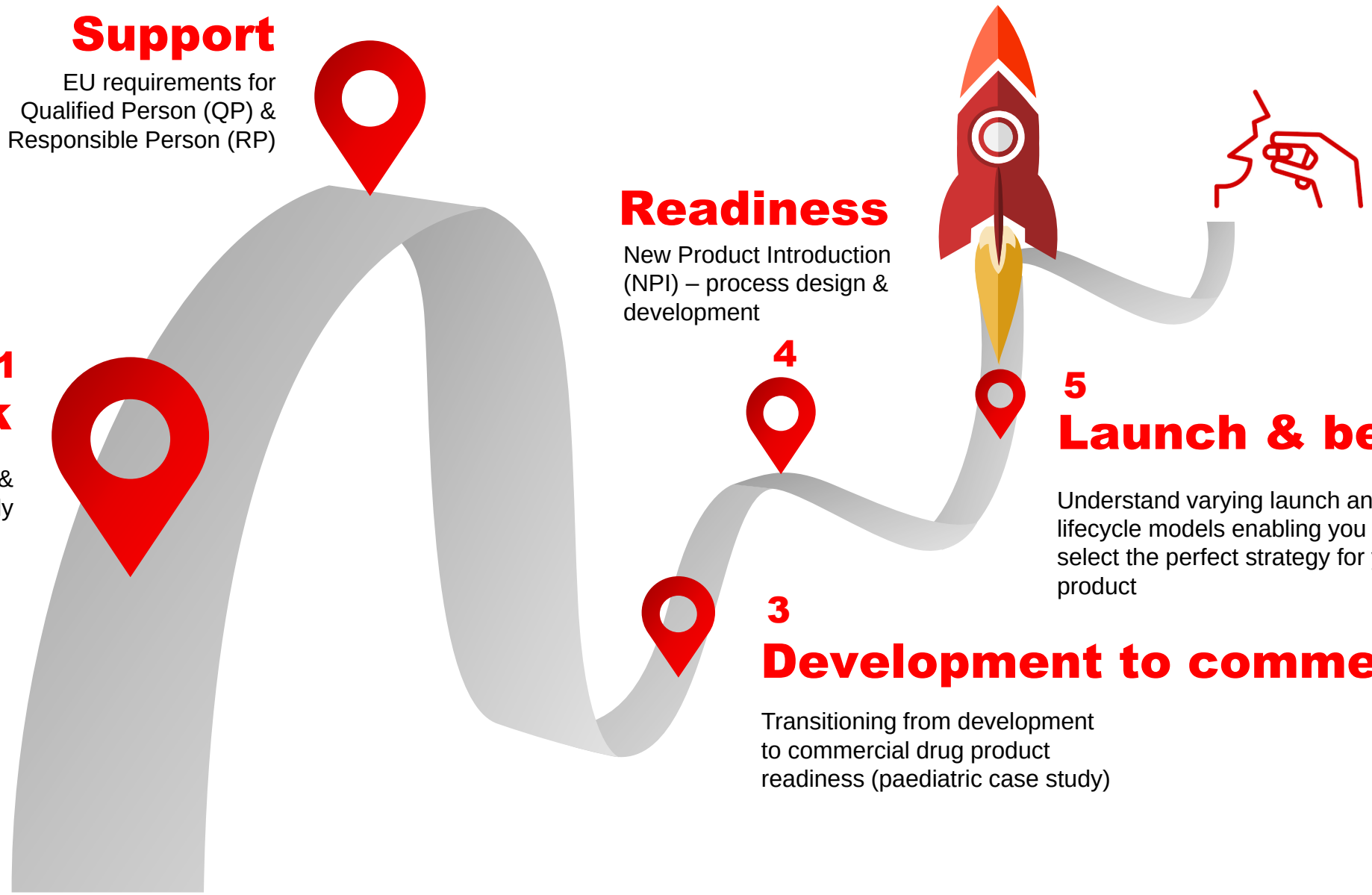
Transitioning from development to commercial drug product readiness (paediatric case study)

4 Readiness

New Product Introduction (NPI) – process design & development

5 Launch & beyond

Understand varying launch and lifecycle models enabling you to select the perfect strategy for your product



Journey to Product Launch Success with Almac

2
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Readiness

New Product Introduction (NPI) – process design & development

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NPI Considerations

Communication strategy

Availability of material for validation

Serialisation

Flexibility

Initial planning

Approval timelines

Packaging design

Supply chain requirements

Validation approach

Launch strategy

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Serialisation

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Launch requirements

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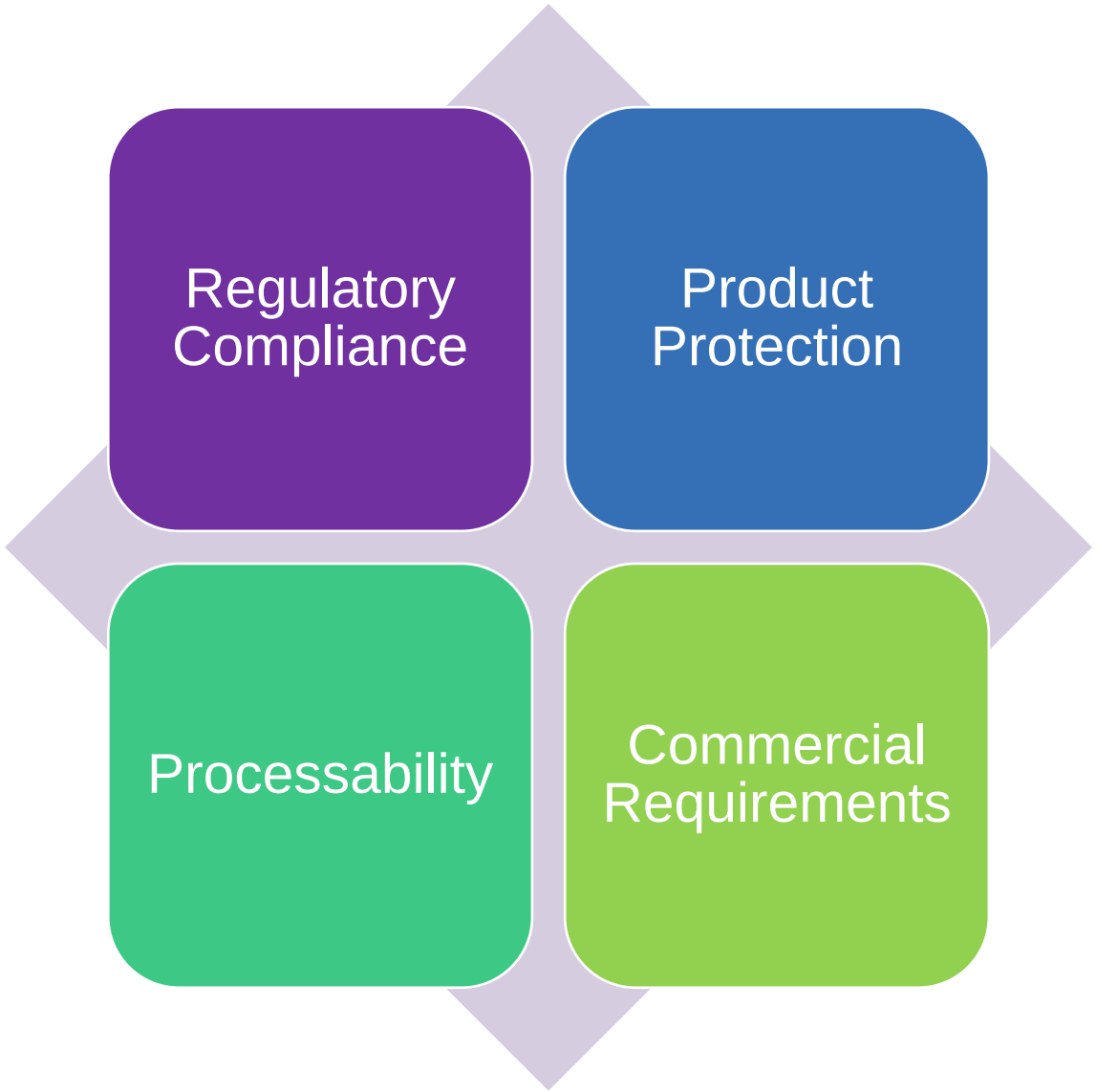
Packaging Design

Packaging – Considerations



Regulatory Compliance

- Readability
  - Font size
  - Font Type
- Braille
- Serialisation
- Senior friendly
- Child resistance
  - F Value

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Partnering to Advance Human Health

Q&A

What Does "Child-Resistant Packaging" Mean?

Q&A with Stuart Hunter, Packaging Design Manager

What Does "Child-Resistant Packaging" Mean?

Child-resistant packaging integrates the use of safety mechanisms and physical barriers to make it significantly more difficult for children to gain access to toxic or harmful substances. The term "child resistant packaging" refers to packaging that complies with one of the standards outlined below:

- BS EN ISO 8317:2004: The international standard covering re-closable packaging for any contents.
- BS EN 14375:2003: The European standard covering non re-closable packaging for medicines.
- BS EN 862:2005: The European standard covering non re-closable packaging for non-medicines.
- 16 CFR 1700.20: The US regulation covering re-closable and non-re-closable packaging applicable to both medicines and non-medicines.

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When does a product have to conform to child resistant packaging?

Medicinal products presented as capsules and tablets are often colourful in appereance, which can appeal to young children therefore increasing the likelyhood of ingestion. By engineering child resistant pack solutions and introducing mechanisms that make it more difficult for children to gain access to such medicines helps reduce the potential risk of ingestion.

According to legislation, once a product is deemed poisonous when inhaled or swallowed, or cause skin corrosion it must be packed within child resistant packaging. In Europe examples of products that must adhere to this legislation would be medicinal products that contain substances such as paracetamol, aspirin or more than 24mg of iron. In the US, the list is more extensive and includes anything that requires a doctors prescription and certain OTC products that include specific amounts of aspirin, acetaminophen, ibuprofen, iron and fluoride.

How child-resistant must a product be?

The extent of how child-resistant a pack format must be very much depends on the contents. A child reistant pack is given a rating, with F1 being the most difficult for a child to open and for example F8 being easier. Medicinal products that are deemed extremely harmful to children would be contained within F1 rated packaging whereas products that are less harmful would be contained within packaging that has a lower rating. F1 rated packaging must use mechanisms that are extremely difficult for children to gain access to as many products contained within this packaging are lethal at one dose, whereas F8 packaging does not require the same level of resistance as products contained within this packaging are not deemed as harmful.

How is child-resistance achieved?

Child-resistance can be achieved by using either a unique opening mechanism or by utilising difficult-to-open proceedures. The following are examples of child-resistant components:

- Performing two movements simultaneously which is required to open the pack. For example squeezing a bottle closure while turning.
- Plastic films or foils, e.g. blister packaging that must be peeled and pulled to be opened.
- More than one action is required to open the pack, ensuring the unlocking parts are so far apart that children cannot reach them with the fingers of one hand, for example wallet style packaging that utilises a push and pull mechanism.

In summary, child-resistant packaging typically requires a special process to gain access to the product within the packaging. The opening process has to be too complex for a child to dicifer, yet easily accessable for adults.

How can end-users be sure that packinging is really child-resistant?

End-users are assured that packaging is child-resistant as the packaging undergoes stringent testing by approved bodies against specific test protocols. During the pack design process a blank prototype of the child-resistant pack is created and tested to ensure effectiveness. Typically, a child-resistant test environment will have 200 able-bodied children, aged between 42 and 51 months, attempt to open the pack. A child-resistant pack should be impossible for at least 85% of children to open within 5 minutes and for at least 80% following a silent demonstration.

Insert link to child resistant packaging Q&A

Product Protection

- Primary and secondary packaging
- Product stability
- Moisture sensitivity
- Temperature compatible materials

Commercial Requirements

- Brand identity
- USP
- Anti- counterfeit measures
  - Overt
  - Covert
- Sustainability


САЛИЦИЛОВАЯ КИСЛОТА
Salicylic acid
раствор спиртовой для наружного применения 20 мг/мл
25 мл
САЛИЦИЛОВАЯ КИСЛОТА
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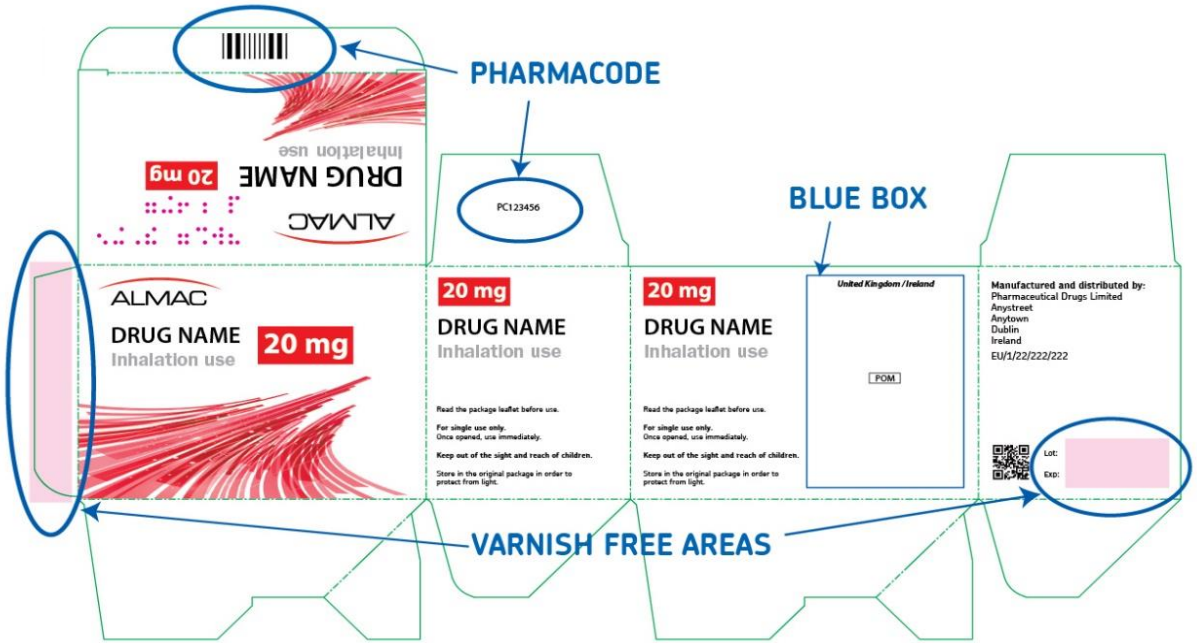
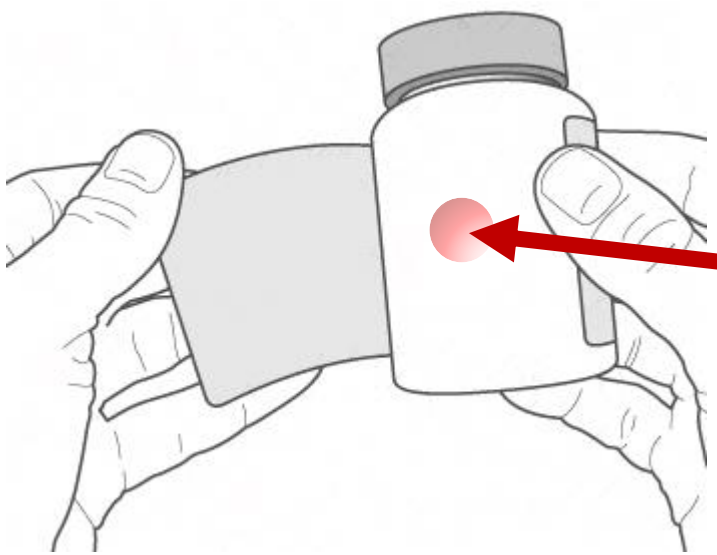

PHARMACODE
PC123456
BLUE BOX
ALMAC
DRUG NAME
Inhalation use
20 mg
20 mg
DRUG NAME
Inhalation use
Read the package leaflet before use.
For single use only.
Once opened, use immediately.
Keep out of the sight and reach of children.
Store in the original package in order to protect from light.
20 mg
DRUG NAME
Inhalation use
Read the package leaflet before use.
For single use only.
Once opened, use immediately.
Keep out of the sight and reach of children.
Store in the original package in order to protect from light.
United Kingdom / Ireland
POM
Manufactured and distributed by:
Pharmaceutical Drugs Limited
Anystreet
Anytown
Dublin
Ireland
EU/1/22/222/222
Lot:
Exp:
VARNISH FREE AREAS

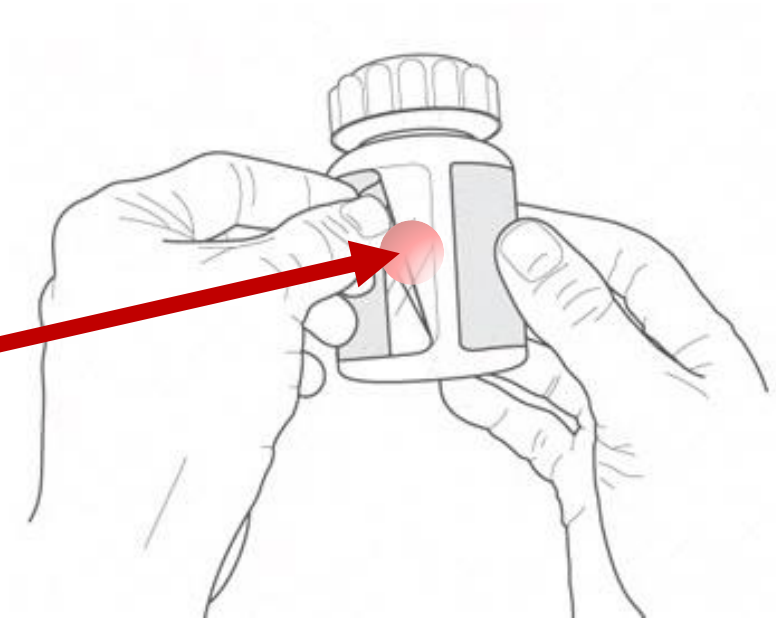
Processability

- Size
- Manual or automated process
- Material of construction
- Cost and lead time
- Single or multi-language presentation

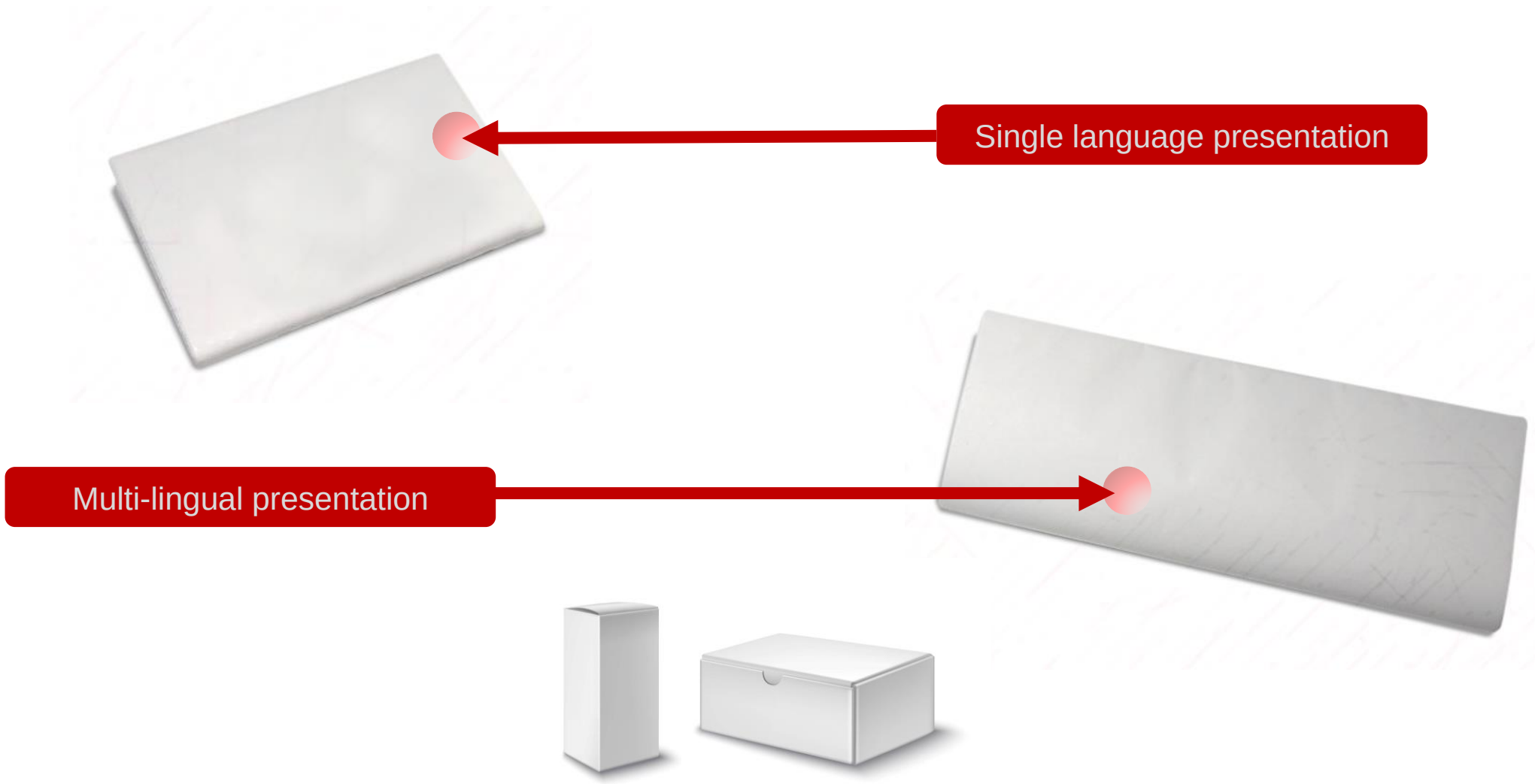

Multi-lingual presentation
Single language presentation

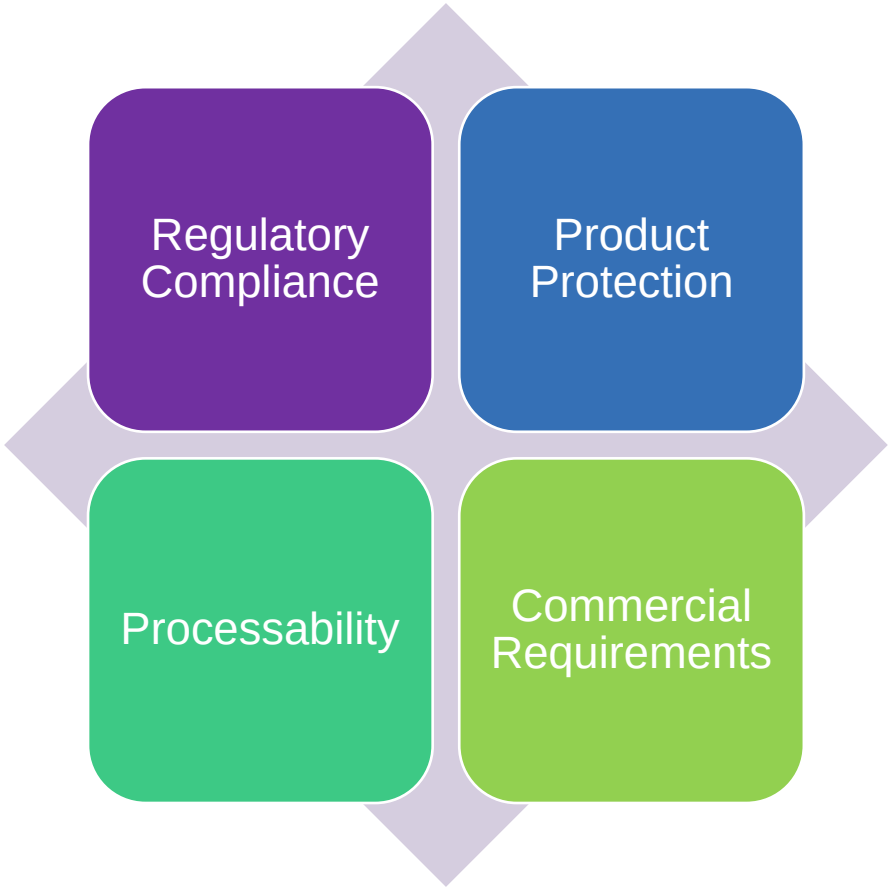


Single language presentation



Multi-lingual presentation


Single language presentation
Multi-lingual presentation



- There are a number of considerations when thinking about the packaging design for your product.
- Carefully balance meeting regulatory requirements with ensuring packs can be easily processed.

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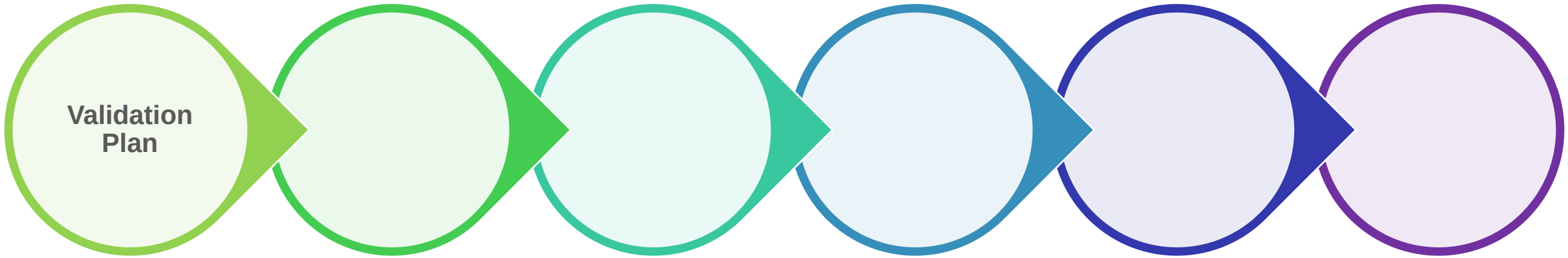
Packaging Process Validation

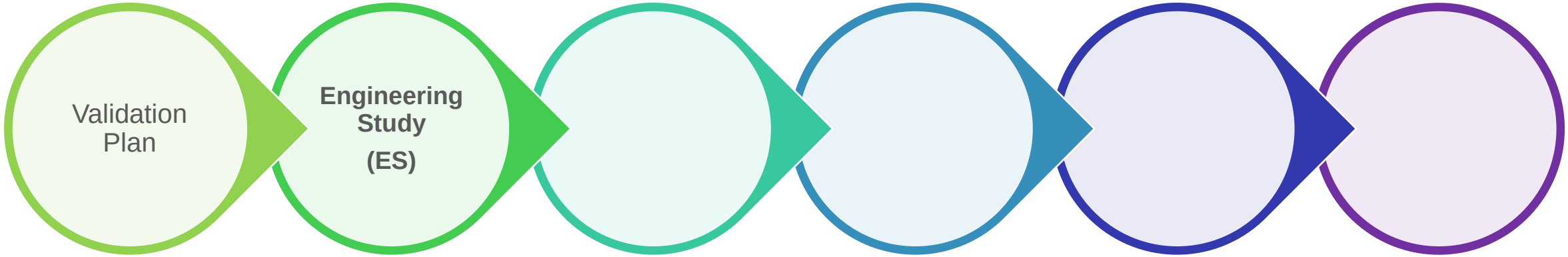
Validation Strategy

- Packaging design
- Equipment
- Material
- Attitude to risk
- Timeline

Almac Packaging Validation Approach

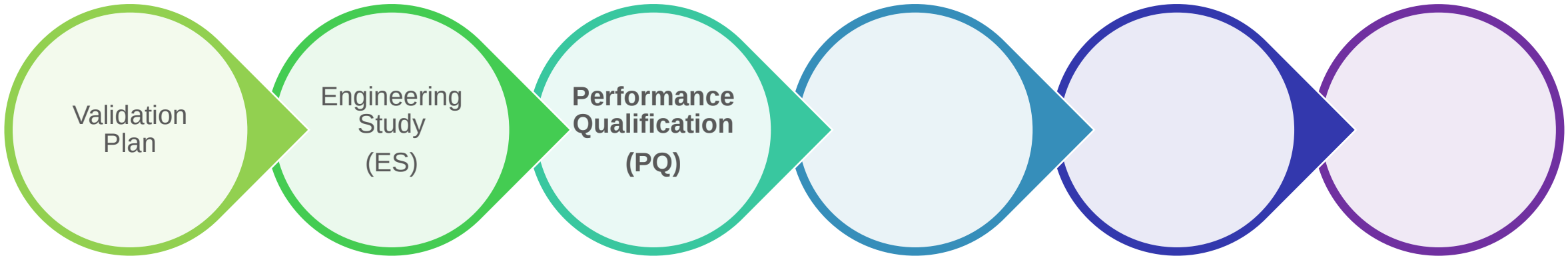


- Plan on a page
- Details the approach to be taken to demonstrate a successful validation
- Defines
  - Critical Quality Attributes
  - Equipment train
  - Packaging material

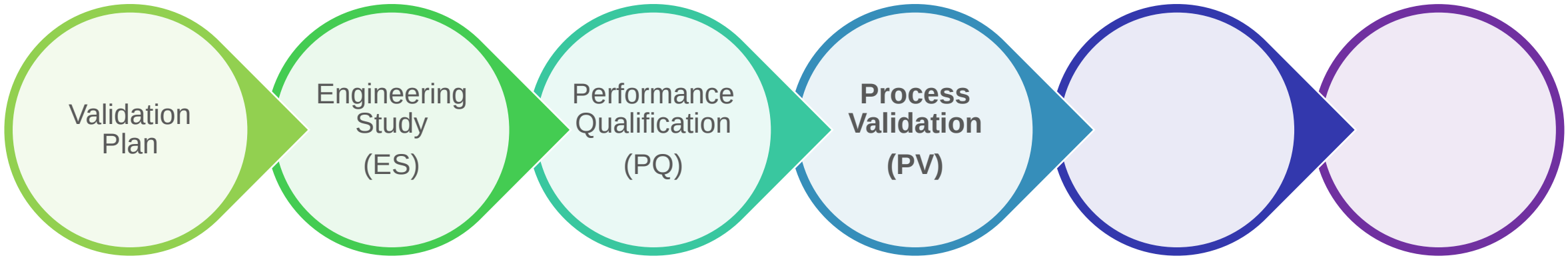

Validation Plan
Engineering Study (ES)

Engineering Study (ES)

- Test and define machine parameters
- Ensure packaging material is compatible with equipment
- Component fit test

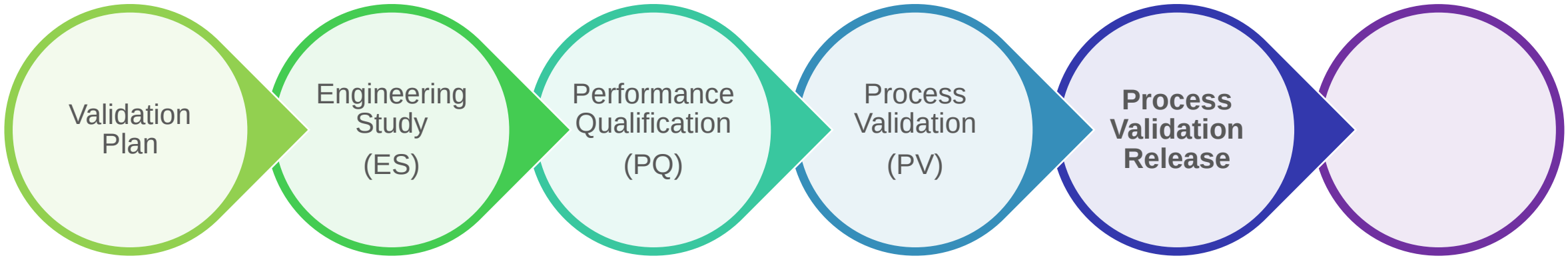

Validation Plan
Engineering Study (ES)
Performance Qualification (PQ)

- Test full equipment train
- Process at extremities of the operating ranges
- Operate alongside draft master batch record
- Serialisation performance qualification


Validation Plan
Engineering Study (ES)
Performance Qualification (PQ)
Process Validation (PV)

Process Validation (PV)

- Test final commercial process
- Routine conditions
- Approved master batch record
- Can be commercial or non-commercial batches


Validation Plan
Engineering Study (ES)
Performance Qualification (PQ)
Process Validation (PV)
Process Validation Release

- Process specification and control strategy (PSC)
- Defines
  - Equipment train
  - Packaging materials
  - QCAs
- Releases the packaging process for routine commercial use

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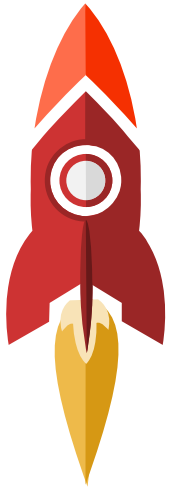

Validation Plan

Engineering Study (ES)

Performance Qualification (PQ)

Process Validation (PV)

Process Validation Release

Launch

Packaging Validation Strategy

- Almac have a robust approach to New Product Introductions and packaging validation
- Important to be flexible
- Problems will occur, changes will happen; adaptability is important!

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Supply Chain Requirements


Drug Substance
Manufacture
India

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Primary and Secondary Packaging Craigavon

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Supply Chains can be complicated…..

- Be aware of import and export requirements when moving product between jurisdictions
- Are there product testing implications?
- Are there restrictions on importing unapproved products?
  - e.g. Pre-Launch Activities Importation Requests (PLAIR)
- Does your supply chain need to be qualified?
  - Route qualification
  - Dummy shipments
  - Distribution testing

….all of these will impact on your timelines!

Almac offer support to qualify your supply chain

Supply chain risk assessment

Test shipments (live or dummy)

Final report

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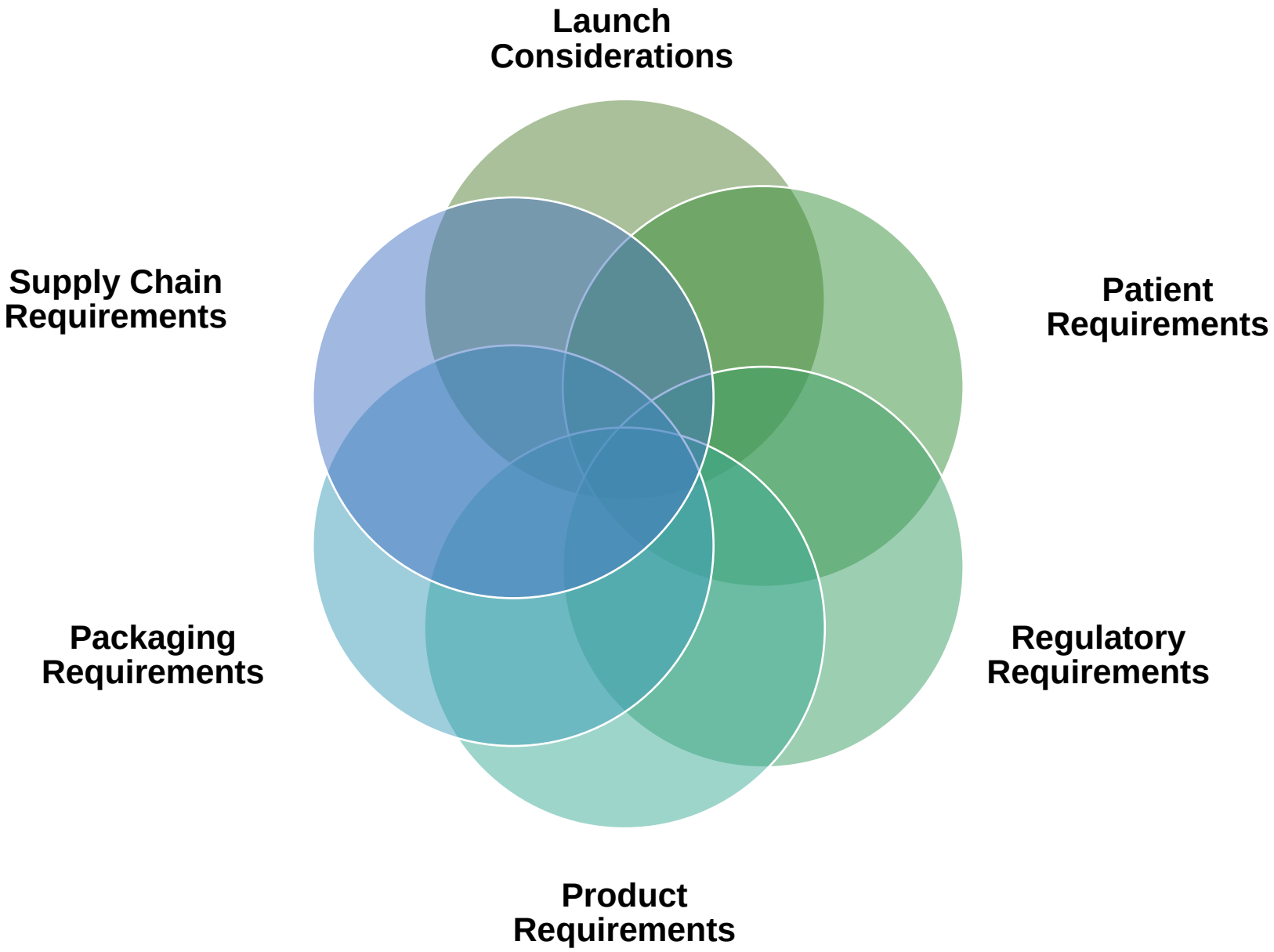
Final Thoughts

NPI - Successful Path to Product Launch



NPI - Successful Path to Product Launch

Understand your timeline

Have a clear communication plan

Rely on expert opinion

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Questions