Product Development for the Developing World

– An Industry Perspective

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Some of the Lessons Learned

- Making the Business Case Internally
  - Need to have Corporate commitment & advocacy
  - Need to have a good Business model
  - Need to have the right conditions; company doing well so you can satisfy stakeholders and invest in lower return projects
- Developing world needs more than a test
  - Training & Support; increases costs but necessary for success
  - Reliable supply; complex processes (e.g. import/customs/duties) and difficult supply chain
- Regulatory environment is changing
  - Fewer non-regulated countries; approval in country of origin becoming more common for developing world
  - Country-specific requirements; no standard in developing world regions as there is in other major markets

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Some of the Challenges – Product Development

- What's needed vs what can be done at an acceptable price point
  - Ease of use often costs more
  - Tradeoffs are required
- Developing World is not one market
  - No one-size-fits-all product; need to segment the market
  - Varies by region & by country
  - WHO is influential, but every country sets own guidelines
- Diagnostics Product Development is complex
  - Highly integrated process
  - Process is as important as product
  - FDA requirements are reasonable for CD4 products; we would do 95% of the work anyway for a clinically validated test

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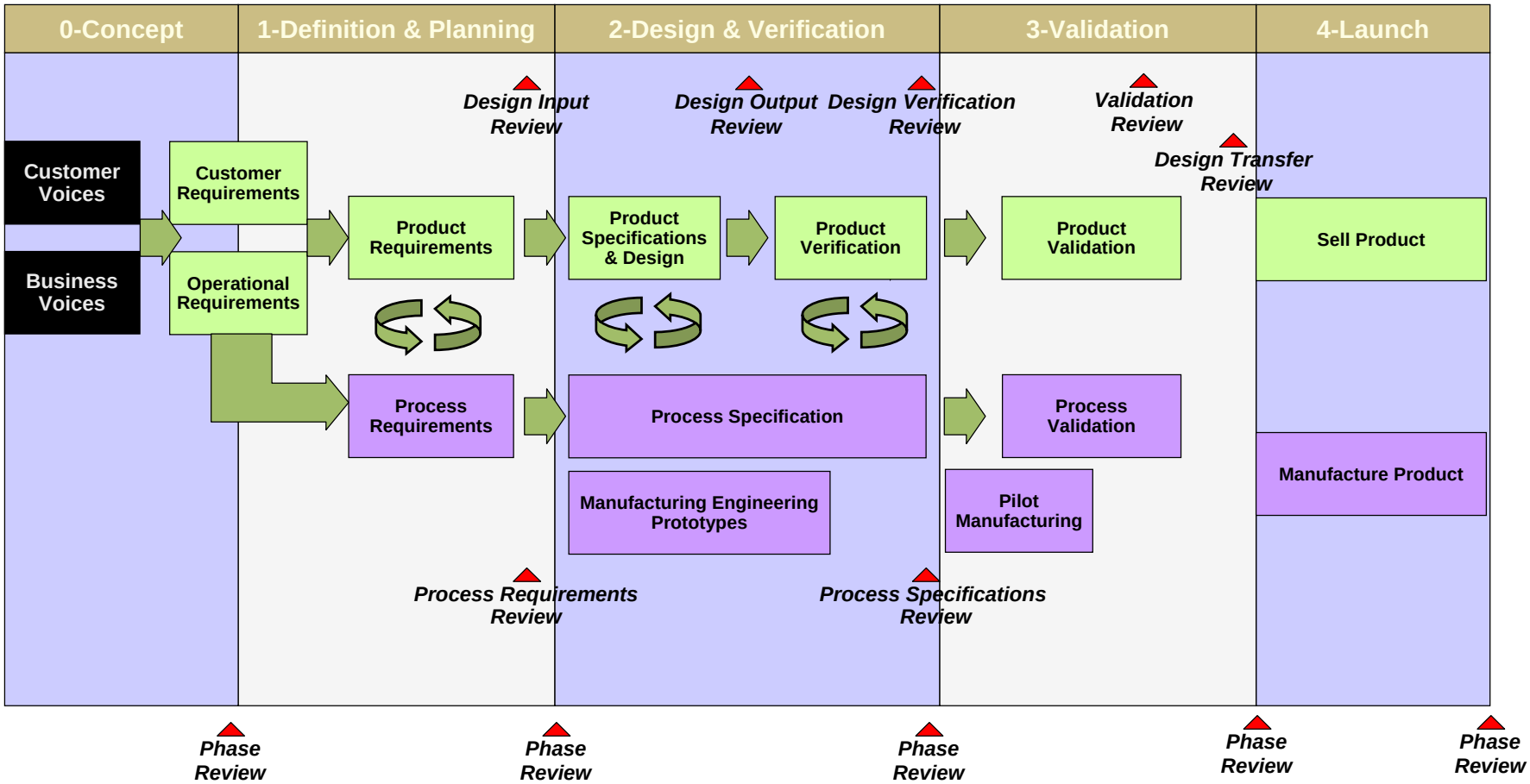
Product Development Process Overview



Market Segmentation

Customer Needs depend on market segment

- Define by Ring
- Prioritize by Ring

Some Example Attributes to consider:

• **Location**	• **Patient Volume**	• **Skill Level of Operator/HCW**	• **Physical Infrastructure**
• **Environment**	• **Patient Access**	• **Price**	• **Ease-of-use**
• **Reliability**	• **Performance**	• **Cold Chain**	• **Training Needs**
• **Sample Stability**	• **Size**	• **Data Management**	• **EQA**

Setting Specifications

Then, you need the detailed specifications for each.

Example of Details Needed for Performance Attribute:

• **Precision**	• **Accuracy**
• **Between Device Variation**	• **Between Lab Variation**
• **Reportable Range**	• **Linearity**
• **Staining Time**	• **Throughput**
• **Age of Stain**	• **Age of Blood**

Recent Example: More than 50 items for all attributes, plus Workflow/Use Cases and User Interface definition.

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Setting Specifications – cont'd

Evaluating Potential Solutions:

Doesn't meet min req	Unknown

Customer Requirements			Solution		
Requirement	Ideal	Minimum	#1	#2	#3
Cost #1 - Consumable	< $x.xx	< $y.yy	TBD	>$y.yy	<$x.xx
Operation #1 - Number of Steps	1	3	2	1	4
Performance #1 - Reportable Range	50 - 5000 cells/ul	100 - 500 cells/ul	100 - 5000 cells/ul	50 - 1000 cells/ul	TBD
Performance #2 - Precision	<10% CV	<20% CV	15%	8%	25%
Environment #1 - Cold Chain	Not Req'd	Not Req'd	Not Req'd	Req'd	Not Req'd
Performance #3 - Staining Time	< 5 minutes	< 10 minutes	12	6	7
Performance #4 - Throughput	> 50 tests/hour	> 30 tests/hour	55	40	20

List Requirements, Prioritize and Compare

Summary – Good Specs are the key…

- **To meeting the customer's needs**
- **To focusing on the important attributes**
- **To knowing what to test**
- **To knowing when you're done!**

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