

Global Product Strategy

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Overview

- Strategy vs. Plans
- Product
- Regulators
- Internal Partners
- Secondary Gains

Strategy vs. plans

- High lever and long term
 - Tactical/operational
- Investigation and learning time
 - Implementation time
- Initiated very early; pre-product freeze
 - Changing with product evolution
- Broad engagement across the company
 - Focused execution partners

Know the product

- Product vs. platform; long term company goal
- Target patients and health care providers
- Competitors; drugs, devices, biotech, procedures
- Experiences in the markets

Before you set your strategy

Know your regulators

- Which markets are targeted/interested?
- Do any of the markets build on each other?
- Which regulators lead in this field?
- How is the product regulated? Class? Data Requirements? Clinical data? Post-market?
- What are the timeframes for work before the actual submission? For submission review?
- Costs?

Engage ALL internal partners

- Early and often!
- ALL partners; business (product/geography), financial, regulatory, quality, clinical, operations, reimbursement
- Be ON the product development team
- Set up internal communications plans

Secondary Gains

“if you do this well”

- Be a real business partner, not the block at the end of the road
- Influence the regulation of the product through engagement of the regulators; a partner
- Anticipate problems and adjust the strategy; lead



Questions?