

Regulatory Strategy in Context

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What is a Regulatory Strategy?

- A strategy is a high level document, as distinct from a plan which contains more detail
- Regulatory Strategy is influenced by many aspects of the business
- The Regulatory Plan is a subset of the project plan and is developed from the regulatory strategy, in consultation with the project team.

Planning is bringing the future into the present so that you can do something about it now.

Alan Larkein



Elements of Strategizing and Planning

- Company Strategy
- Project Strategy – a subset of company strategy
- Product Profile – an output of the project strategy
- Reimbursement strategy
- Development Plan – an output of the project strategy and product profile
- Regulatory Strategy – a subset of project strategy and product profile
- Regulatory Plan – a subset of the development plan
- Regulatory Communication Plan – a subset of the regulatory plan



The Company Strategy

- Board driven
- Risk appetite
- Business strategy
- Product Pipeline
- Project priorities
- Funding options/timing
- Exit strategy



"... Wait a moment, I need to review my exit strategy."



The Project Strategy

- Driven by the Board and Senior Management Team
- What is the end goal for the project?
- Develop to registration?
- Partner after Phase I, 2?
- Out-license further development at end Phase I, 2?
- Outsource most of development work or do in-house?
- Manufacture clinical trial supplies or outsource?



Product Profile

- What are you aiming for?
- How will your concept look in the pharmacy?
- What is the PRODUCT?



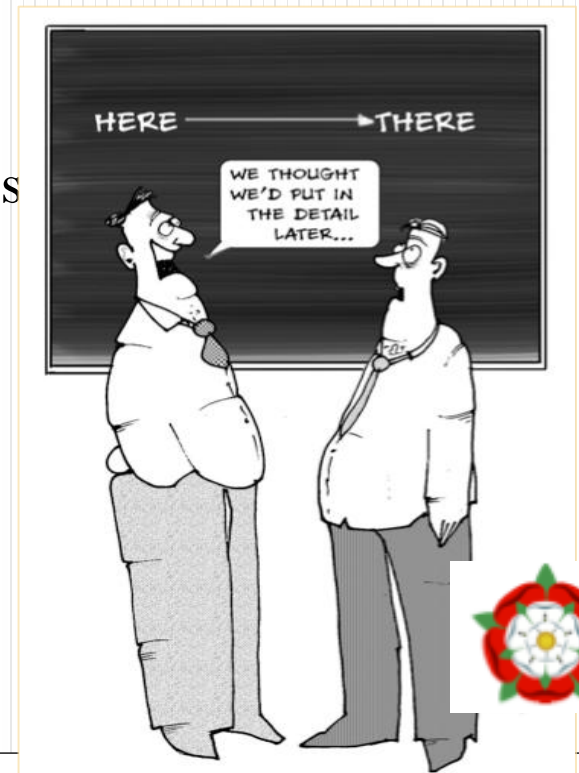
The Product Profile

- Therapeutic area
- Indication
- Dosage form
- Delivery system
- Drug or device combination or drug/device combination
- Single or multiple strengths/presentations/types
- Storage conditions/stability/shelf life
- Other key attributes



The Development Plan

- Inertia is your enemy and so is time
- You're in a race and it's a marathon
- Determine major milestones first
- Progressively fill in details
- Seek input from each area of the business
- Continuity of thinking around goals
- A good plan is dynamic and evolving



The Project Team



The Project Team

- Multi-skilled
- Involvement of Regulatory representative as early as possible
- Regulatory / CMC expertise needed from the beginning
- An appreciation of information management is vital
- If outsourcing, choose consultants wisely and have a clear communication plan and deliverables



The Project Team

- Do a skills analysis on the team
- Does the project team have all the required skills to progress at the desired pace AND at the desired level of quality?
- If not, what can you do?
 - Up-skill or retrain existing staff
 - Hire more or replacement staff
 - Contract in
 - Contract out



The Project Team

- There must be a level of trust within the team and commitment to a shared vision
- The team must be able to:
 - Discuss positives and negatives
 - Reflect on experiences
 - Learn from experiences and be able to apply that knowledge
 - Celebrate successes
 - Slow down at times – it's not a sprint race
- Morale is important in marathons



The Project Team

- Have:
 - clear responsibilities
 - clear accountabilities
 - reasonable delegation of duties and decision making
 - a clear communication plan
 - Regular meetings
 - Ad hoc meetings of whole team or subgroups as needed for firefighting or to take advantage of opportunities as they arise
 - Consultants and contractors who function as part of the team and have buy-in to goals



The Project Team

- Relevant experience is vital
- You don't know what you don't know

*This is the single biggest risk to project success
that is within your control*



Intelligence Gathering

- Business, regulatory and political
- Monitor global trends
- Regulatory and quality hot topics
- Regulator websites
- Competitors
- Emerging trends, new technology
- International conferences
- Do not develop in isolation



Risk Management

- Know what risks are and mitigate them
- Expert advice can be vital in identifying risks and gaps in the project plan
- Develop a risk register with actions
- Review risks regularly, they will change over the lifetime of the project



Regulatory Strategy

- Elements of a regulatory strategy include:
 - Regions and countries targeted (initially and later)
 - The product profile
 - Exit strategy
 - First engagement with regulatory agency (which/when/who/how)
 - CMC strategy
 - Pre-clinical strategy
 - Clinical strategy



Regulatory Strategy

- To IND or not to IND? (To IDE or not to IDE?)
- When is the right time to enter into an IND/IDE?
- What are the drivers for this?
 - Need for feedback and clarity for investors
 - Trial sites in USA
 - If first trial done outside of US, option to wait but beware of potential data acceptability issues and demographics



Regulatory Strategy

- Paediatric investigational plans
- Risk Management Plans –flavour of the month
- Patents and exclusivity considerations
- Evolving Regulatory environments



"Our research shows that heredity and environment are both very significant, but that neither is as important as government regulation."



Take Home Messages

- There are lots of inputs into a regulatory strategy
- All strategies and and plans are dynamic and will evolve over time
- The project team's collective wisdom is greater than the sum of its members
- Stay up to date with emerging trends
- **The fundamental interconnectedness of all things within the project cannot be underestimated**



And Finally...

Forewarned, forearmed; to be prepared is
half the victory.

Miguel de Cervantes Saavedra 1547-1616

