iFormulate

Introduces

Design for Formulation- concept to reality

Increase your productivity!

David Calvert & Ian Jolliffe

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Your Speakers

- David Calvert

- Ian Jolliffe

- **This webinar is being recorded and will be made available**

YouTube GB

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A Little About Us

- A company founded in 2012 by two experienced industry professionals
- Combining diverse experiences, knowledge and wide range of contacts:
- …polymers, materials science, chemistry, imaging, dyes, pigments, emulsion polymerisation, biocides, anti-counterfeiting, environmental, formulation, consultancy, marketing, business development, strategy, regulatory, training, events, R&D, innovation
- Complementary network of associates

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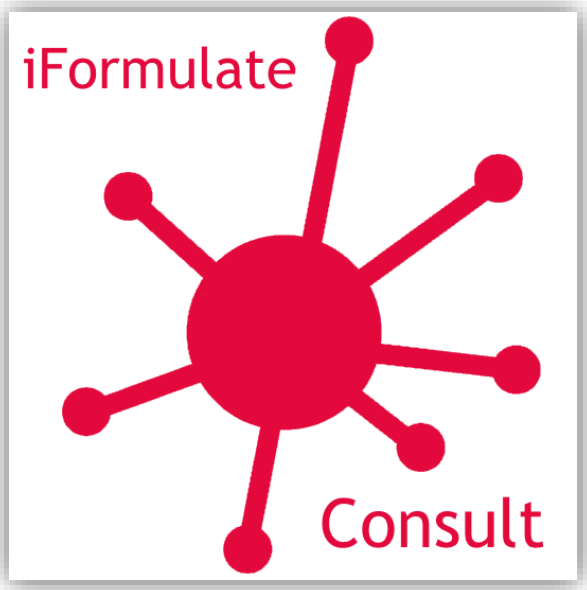
Our Services



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What are Formulators trying to achieve?

- Three goals that formulators must deliver:
  - Product that meets the business brief
    - Claims
    - Costs
  - Robust manufacturing
    - Process that works first time and every time
      - Copes with changes in equipment or site
      - Copes with changes in raw material properties/supply
  - Regulatory requirements are met
    - The required data and knowledge
    - Presented in correct way that is easy assimilated
    - No issues if the process is under inspection
      - Quality standards ISO, Specific industry regulations
      - Adverse product reactions /accidents in use

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What are Formulators trying to achieve?

- Product understanding and knowledge base
  - Basis of INFORMED decisions
  - Foundations of new products
- AGAINST a background of TIME and RESOURCE pressures
  - *we need to improve our productivity!*

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Possible Consequences of a loosely /un-structured development process

- Late stage product failure- missed launch dates
  - won't process reliably, claims not met, costs too high
- No flexibility
  - changes in manufacturing site, process equipment
    - eg what do you do if the only piece of kit that works breaks down?
  - Starting material changes
    - Change in supplier site
    - Cheaper suppliers

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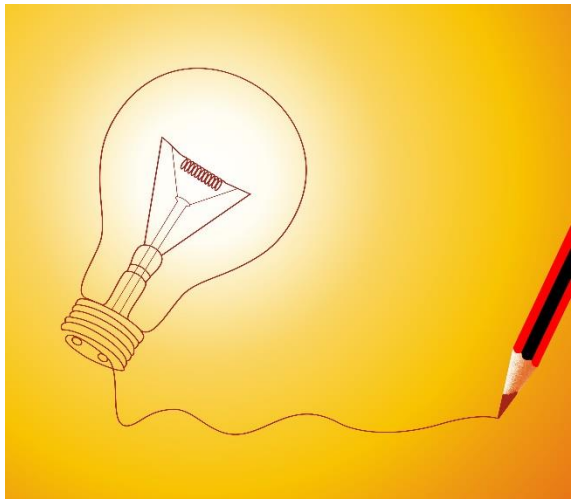
Possible Consequences of a loosely /un-structured development process

- Wrong facility and equipment bought
- Doing more testing than you need to
- R&D doing more trouble shooting when they should be developing new products
- Loss of Expertise and Experts
  - Loss of Understanding and rationale of how and why product was developed in a particular way
  - Lose Knowledge base and learnings – wasted time starting from scratch!



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Structured approaches in different industries

- Healthcare /Pharmaceuticals
  - Quality by Design ICHQ8
- Medical Devices
  - Design Controls ISO 13485
    - Procedures should be put in place by manufacturers in order to have a quality system that will comply with MDD 93/42/EEC.
- Engineering
  - Design for Manufacture (DfM)
- General Quality Systems
  - ISO9000 Family
- Six Sigma/ Lean Manufacture
  - Process capability
  - Often post formulation design

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Structured approach

- The same key stages apply across many industries
  - Before you go into the lab -... A few hours thinking must be worth it
    - What are you going to do (and not do) and why? and what are the deliverables?
  - Focussed lab scale programme-.....Let's see what works!
    - Maximising knowledge and information foundation –focussed to minimise work
  - Development /Pilot scale ...the dawn of reality!
    - Processing on real equipment – what options are there?
  - Industrial scale – Real life reality!
  - New products/ enhanced products ... Exploiting the benefits & increase your productivity –one Pharma company claimed it cut their development time by 35%!

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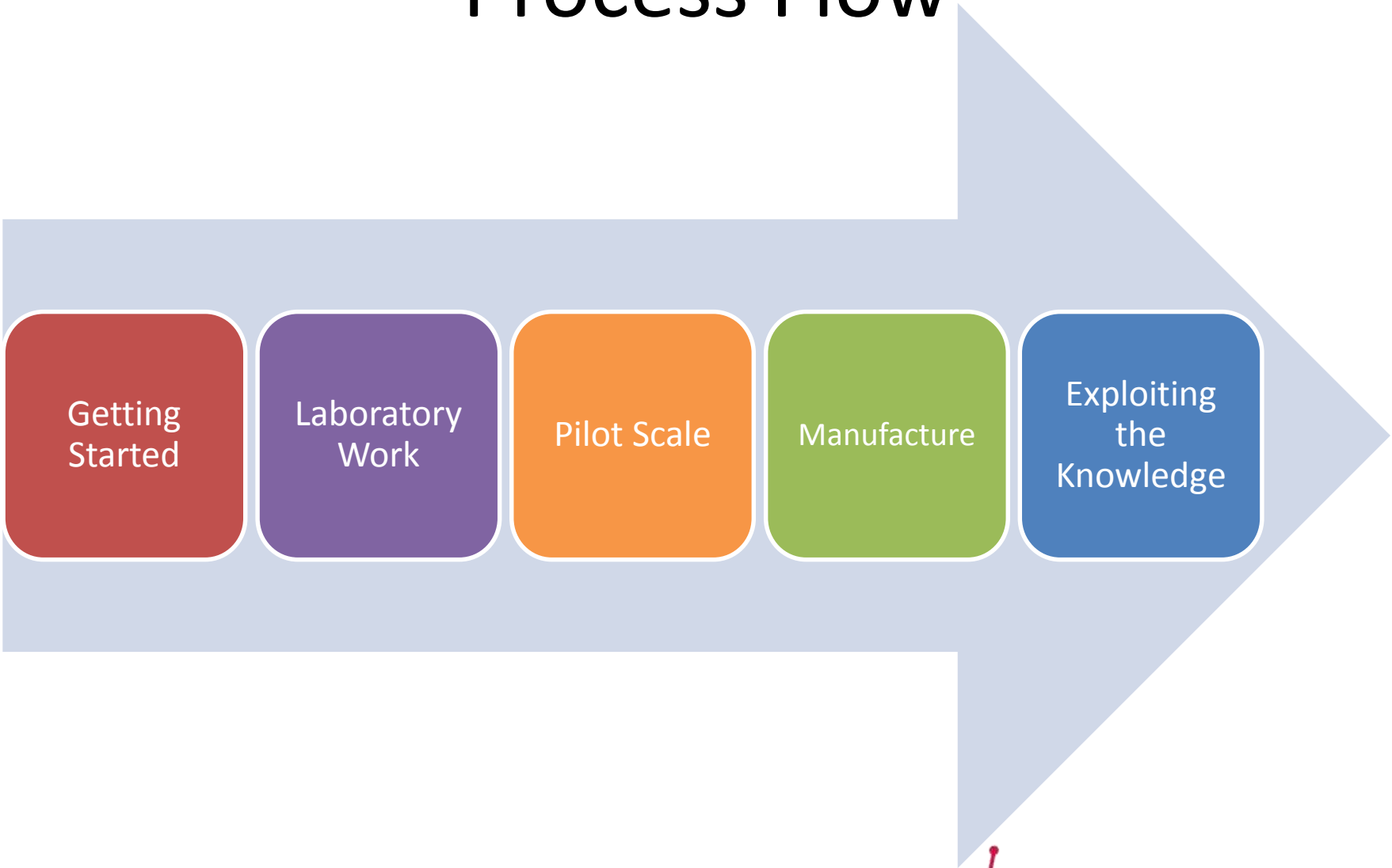
Process Flow



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Getting Started

Getting started -before you go into the lab

- SCOPE
  - Prior knowledge review
  - Preformulation
  - Risk assessments
  - Development strategy
    - What are going to do, how and why?
    - Doing what's critical

- DELIVERABLES
  - Development/Formulation Strategy based on sound foundations
    - Prior knowledge
    - Preliminary experiments
    - Risk assessing to focus on the essentials

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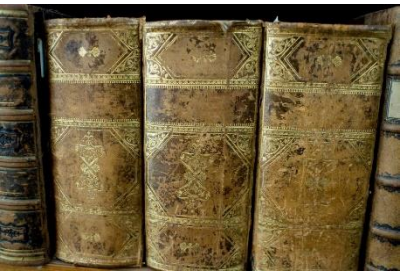
Getting started

Getting Started

- SCOPE
  - Prior knowledge review
  - What other similar products have been developed
    - yours, your competitors
    - Literature including patents [Patents searches will also identify protected ie no-go areas]
    - Experts, local or external, Dragons who will ask the uncomfortable questions!
    - What don't you know? What Preformulation work needs to be carried out?
  - Preformulation
    - A few quick experiments to get some understanding eg. Compatibility stability [....don’t forget pack compatibility]
    - “Scientists job is to observe” Anon | "You can see a lot by just looking.” -- Yogi Berra



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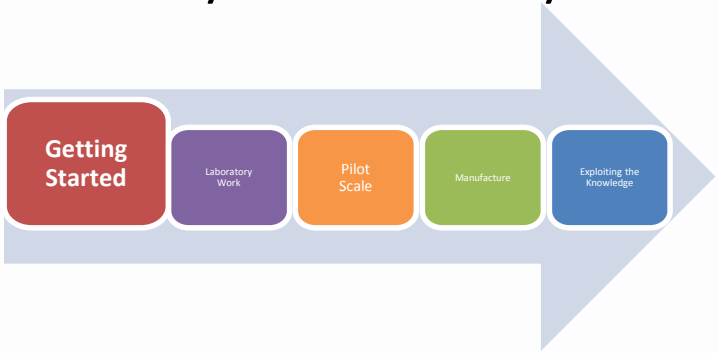
Risk Assessments

- Only as good as knowledge and expertise and openness of minds
- What product and claims are you trying to make? What will you do to provide evidence?
- What will be quality attributes? Which ones are critical? Product specification, what official or industry standards must be met?
- What Material properties will affect the quality attributes? Starting material specification
- What process parameters will affect the Quality attributes and therefore need to be controlled? In process controls
- Over what process ranges and material variation will your product be produced within specification?
- Overall what is your control strategy to ensure you end up with what you want every time?



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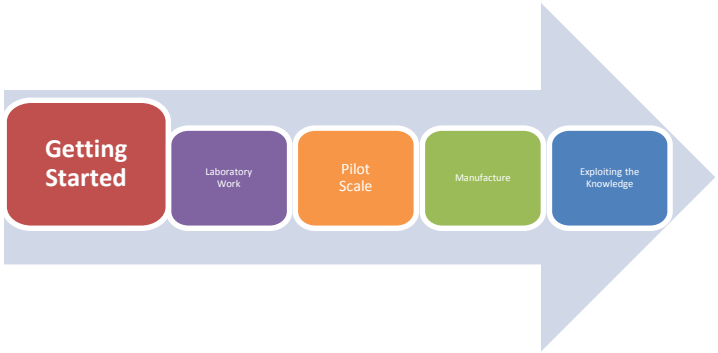
Promise to customer/ CLAIMS	**Painkiller tablet that gets to work in 5 minutes**
Quality Attributes	**Dissolution test eg 80% dissolved in 5 minutes**
Starting Material Attributes	**Fine particle size required to aid dissolution eg particle size specification**
Process Parameters	**A hard tablet could be slow to dissolve eg Tablet hardness specification**
Process Envelope	**Process stretch to explore limits which product which complies with Quality Attributes**
Control Strategy	**What controls will be put in place to ensure the product will fulfil *all* quality attributes/specification. Eg in validation, in-process controls , final product testing**

Development Strategy

- What are you going to do, how and why? Based on your risk assessments
- Efficiency/Productivity
  - Focus on doing what's critical
  - Design of Experiments



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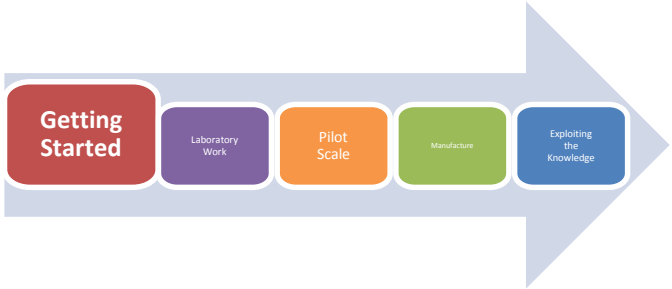
Deliverables

- Development/Formulation strategy based on sound foundations
    - Prior knowledge
    - Preliminary experiments
- Risk assessing to FOCUS on the essentials
    - Risks considered and thought through from starting materials through process to industrialised marketed product
    - Risks justified – basis of assuring Regulators everything is under control & Control Strategy
- Design of experiments
- Altogether = Increased productivity



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What can go wrong?

- We used that formula base before so saves a lot of time let's just use it

  ....but incompatibilities

- Let's solve the incompatibilities by process changes

  .....but process is a knife edge that won't work on industrial scale

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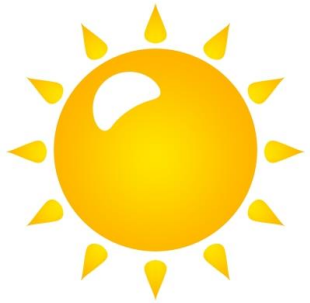
When things go right!



- Thought about product, collected knowledge from a wide range of experts, read about ingredients, set up compatibility studies
- Compatibility issues resolved by careful selection of grades
- Development scale, sighter trials showed critical process points
- Design of experiments to find process envelope
- Trials conducted with production team - success demonstrated

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Future Benefits

- SCOPE
  - Leaning the process
  - Robustness and future proofing
  - Equipment flexibility
  - Starting material flexibility
  - Regulatory agility
  - Basis of continuous improvement
  - Learnings for future products
    - One of a company's biggest assets is it's knowledge base
- DELIVERABLES
  - *Long term benefits of the Design for Formulation approach*
  - *Enhanced productivity*

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Design For Formulation Products and Processes

- Two Days
  - Stand alone
  - 24th September Products
  - 10th December Processes
- East Midlands, UK
- Individual days £395 Plus VAT
- Both days combined £710 plus VAT
- http://iformulate.biz/training-and-events/design-for-formulation/

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Coming up

- Malcolm McKechnie on Cross-Sector Innovation
- Ian Scowen on The Life of a Suspended Particle – Rules and Regulations
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Questions?

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