

“Pharmaceutical Manufacturing - The Next Ten Years for Ireland.....”

CCC/CIT/UCC/IDA meeting

2020 vision – Integrated technical operations in Ireland

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b i o & p h a r m a c e u t i c a l c o n s u l t i n g

Short Bio

Trained as an engineer

Business recovery - instead of an MBA

Pharma Technical Integration assignments in 1990's

Set up own consultancy network in 1996

25 specialists; focus in Development, manufacturing & Quality

> ten years of ongoing client work in Ireland

PharmaPhorum & BioPhorum industry clubs

Married with three children - & Pasha..



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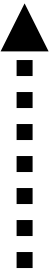
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Technical operations – increasingly strategic...

- **Making technical operations competitive**
 - ▶ **The Steven Wheelwright* Model of Competitiveness**

Externally competitive	-	Drive Business Strategy
Externally Supportive	-	Customer Service Advantage
Internally Supportive	-	Cost Advantage
Internally Neutral	-	Cause No Problems
Internally Negative	-	Quality/Delivery Problems

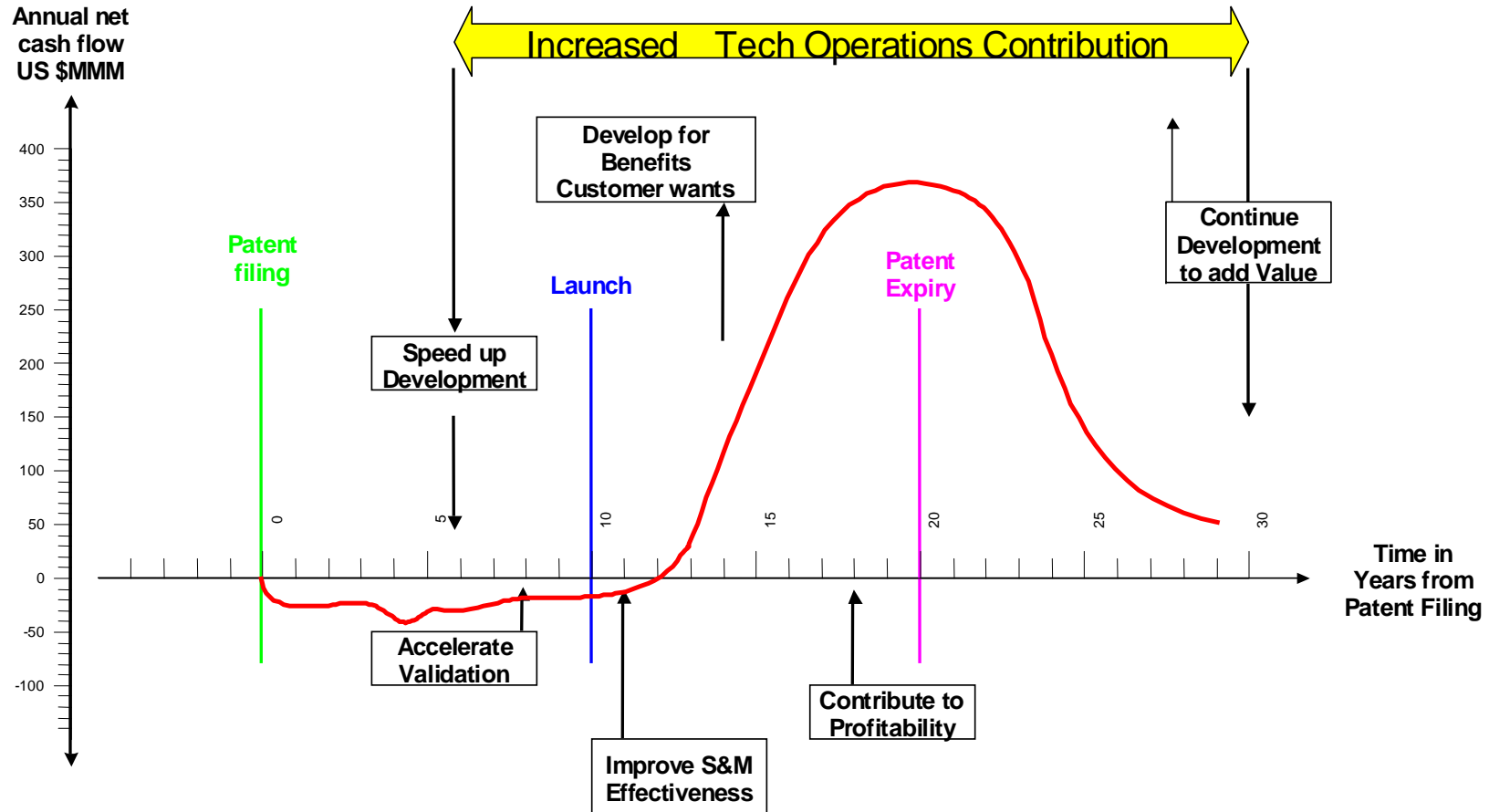


The traditional role of technical operations requires fundamental re-appraisal to ensure that it makes an increasingly strategic contribution.

It will no longer suffice to be "Internally Neutral" we must become at least "Internally supportive" and where possible "Externally supportive/Competitive".



Externally supportive – role of Technical Operations



Tech Operations: Development, Manufacturing & Quality



Becoming - Internally Supportive

Looked at in 'text book' terms, this means focusing on Three core Business processes:-

New product development, registration and launch

Product compliance and process performance through-out the development & supply chain

End of patent life reformulation and patent extension activities.



Becoming - Externally Supportive

Looked at in strategic business terms, this means :-

Accelerating product development, registration and launch – 1000 days?

Enhancing Product compliance and process performance through-out the development & supply chain – QBD/PAT

Undertaking End of patent life reformulation and patent extension activities – 2nd generation synthesis/formulation/device development

Why not...

do all of the above on a commercial site in an integrated manner....

.....in Ireland?



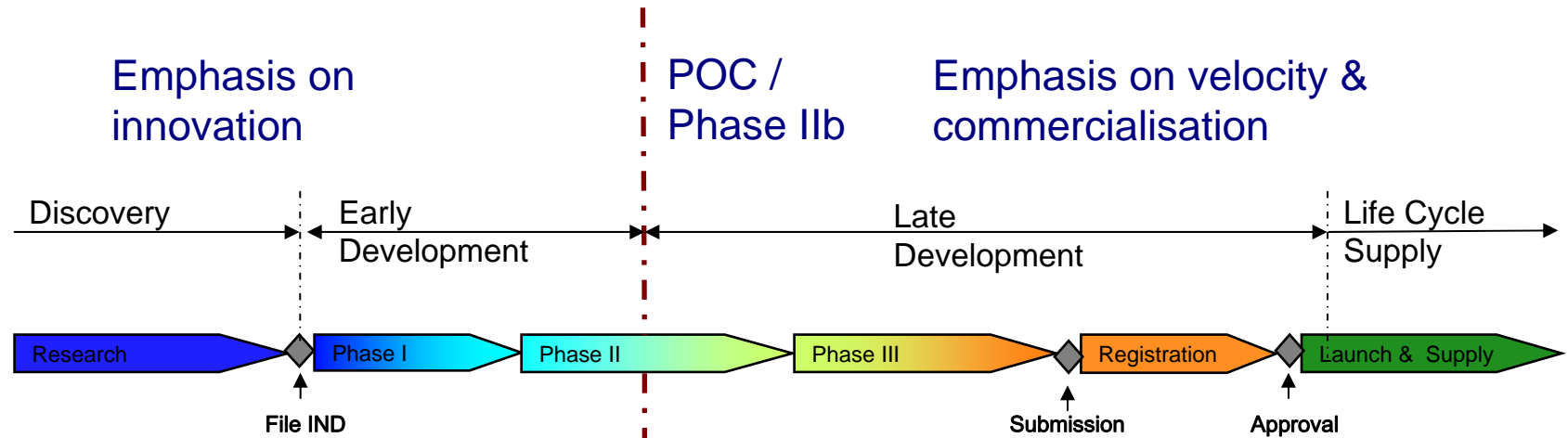
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Research, Development & Manufacturing (RDM)

- Requirements for increased levels of 'pipeline productivity' are driving industry wide restructuring of the R, D & M processes.
 - ▶ This is resulting in the phase I,II,III development model transitioning into an early development and late development model. (ED – LD)



Increasingly the Late stage Development activities are being combined with commercial supply – resulting in Pilot plant investments co-locating with existing supply sites.



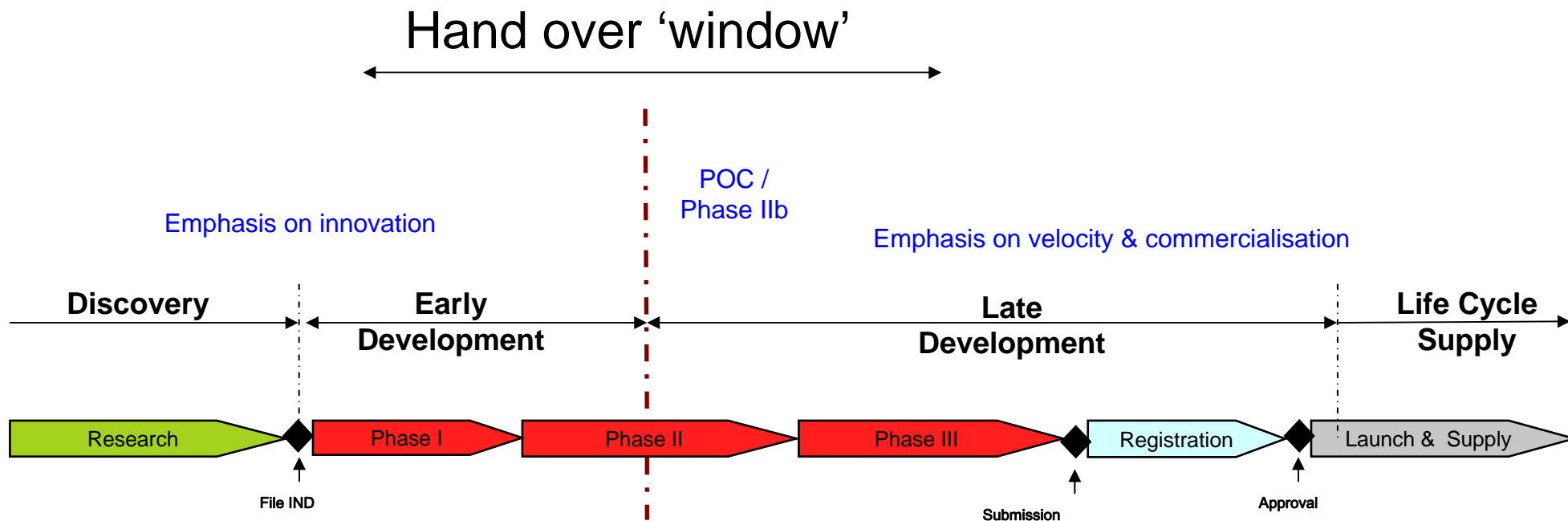
Integration trends

- In tern, the focus of supply sites is transitioning to encompass all aspects of commercialisation
 - ▶ process development, clinical supply, regulatory approvals for launch, global supply & subsequent 2nd generation development and process optimisation.
- A number of technology trends are also emerging as key drivers to commercialisation:-
 - ▶ Extensive use of Quality By Design (as driven by ICH guidelines 8, 9 & 10) enabling robust process development, subsequent regulatory approvals and changes
 - ▶ Emerging use of Process Analytical Technology/continuous production (a key tool associated with QBD) to optimise both product and process efficiencies
- Network consolidation is also forcing sites to increase their value proposition through:-
 - ▶ Often becoming Single global supply site for key franchise products.
 - ▶ Maximising scientific, technical & engineering capabilities with minimum infrastructure or overheads.
 - ▶ High 'project & supply capability' – being trusted to do both - reliably & effectively





Basic Model

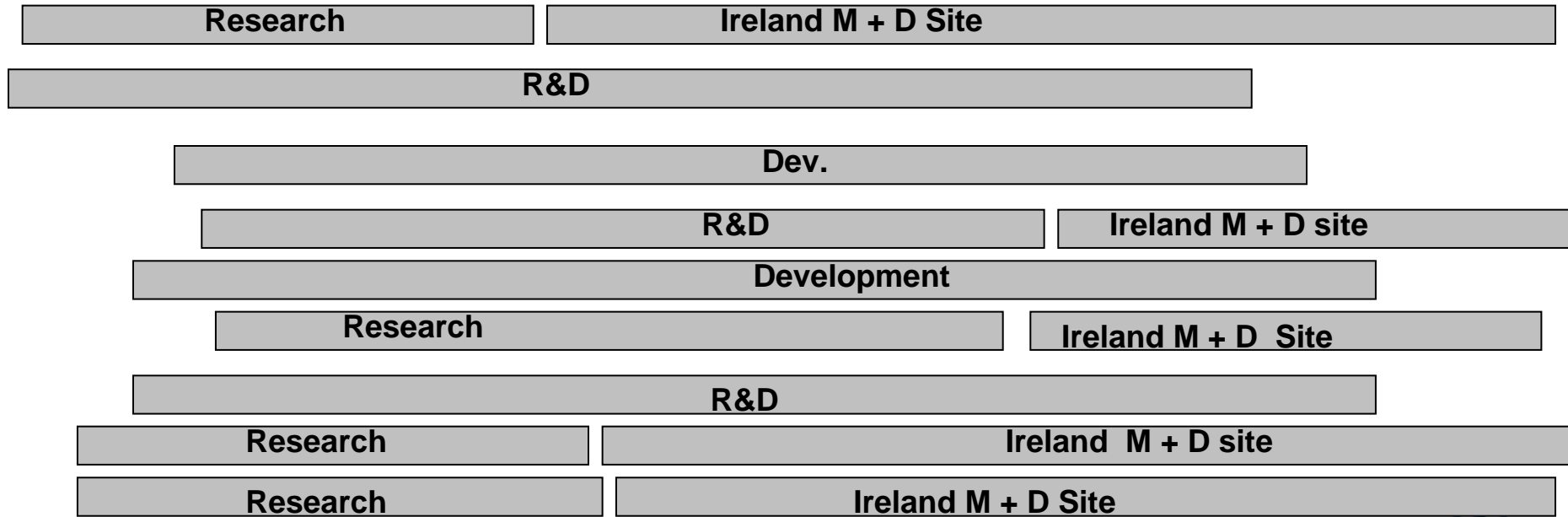
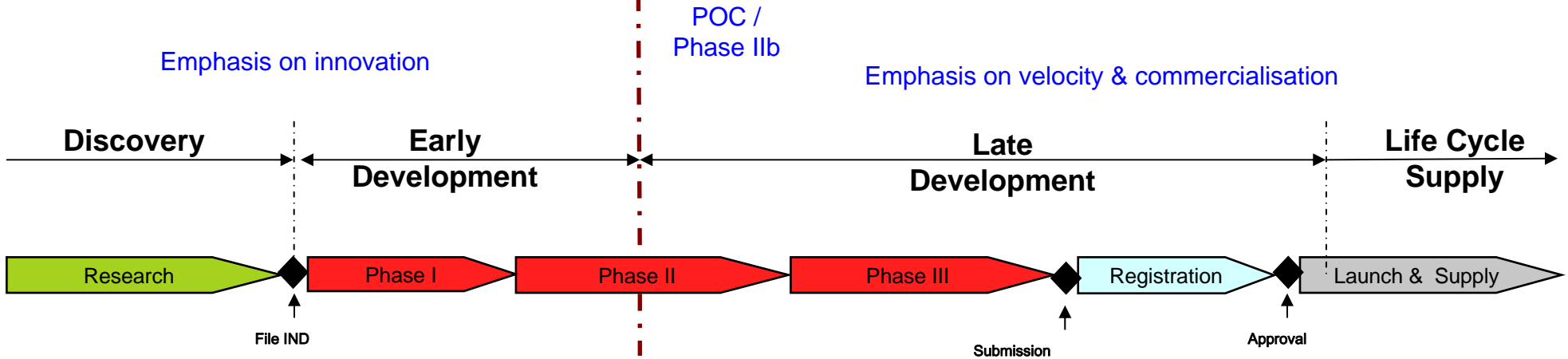


2008 Pharma Phorum – Shared & compared company models

2009 Pharma Phorum – Discuss how you make it happen

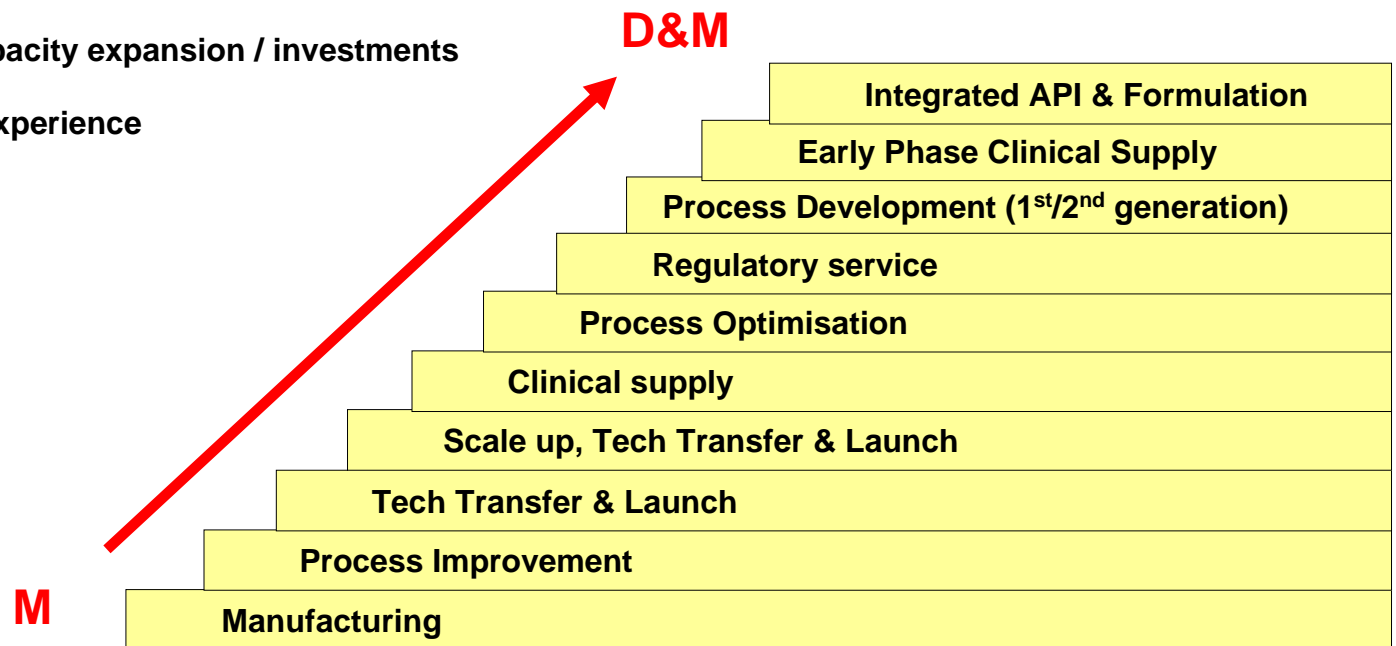


Basic Model Small Molecule – Development Accountability



1. Site specific D&M plans

- A pathway of stepwise activities is common to most sites
- There is a continuum of company situations from 'too early' to first development projects to fully endorsed site D&M strategies
- Key levers include
 - ▶ Utilising manufacturing equipment and facilitates for phase III supply
 - ▶ Maximising development tax credits & IP tax arrangements
 - ▶ Avoiding / delaying capacity expansion / investments
 - ▶ Utilising specific site experience



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6. Re-branding of Ireland – “change the message”

- Industry needs for commercialisation are obviously far more complex than for manufacturing alone
- Recognising and meeting these needs will require messages that appeal to development, regulatory, commercial and manufacturing executives
- Communicating & re-branding Ireland should increasingly include:-
 - ▶ Level of development activities in Ireland
 - ▶ Number of products being developed in Ireland
 - ▶ Number of products being launched in Ireland
 - ▶ Speed & success of registrations
 - ▶ Key process innovations etc
- This branding needs to convey all aspects of commercialisation – manufacturing, development, regulatory, time to market, project management such that Ireland is recognised as the top location in the world from which to commercialise pharmaceuticals
- *‘Bring a molecule (that works in the clinic) to Ireland & we will supply product to the world’*



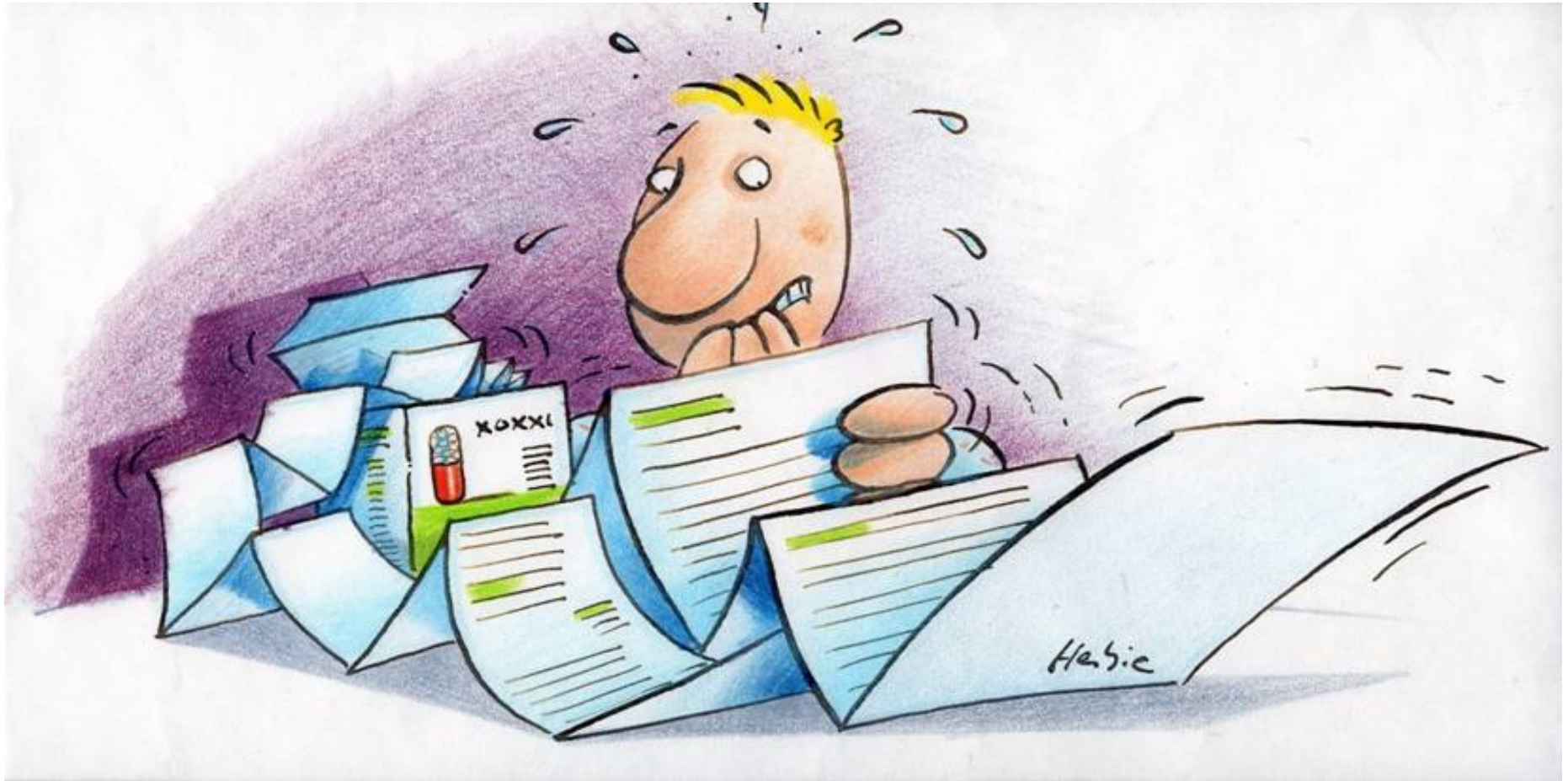
Today.....

Tomorrow

Top tier global supply location	Identity as most effective & business friendly environment – <i>tax + experience + stable</i>
Identity as tax advantaged manufacturing location	Differentiated - as most integrated technical COE for D + M
Predominately supply driven	BOTH supply & development project driven
Volume driven site cost structures	Value driven – optimised cogs + <CMO development costs
Often low/minimal corporate relationships	Innovative, can do, business savvy, networks
Unknown academic institutions	Clone Anita Maguire..... <i>Think Switzerland – not just Boston</i>
Gold standard in site compliance	Gold standard for clinical, regulatory & commercial agency reputation
Experienced ‘safe hands’	Technically experienced teams of innovative, flexible ‘can do’ people people.



Questions?



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