



Medical Product Innovation

Enhancing Antimicrobial Drug Development

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Product Architect

#FDA_AMR

@MPDexpert



Workshop Goals



- * Better understand state of antibacterial drug development
- * Consider **strategies to enhance** antibacterial drug development

Workshop Tactics and . . .



Plan:

Assemble a
diverse array of
Subject Matter
Experts in **ID**

Outlier:

I am a **Subject Matter**
Expert in **MPD**, having
developed a **diverse**
array of global
Manufactured Medical
Products

Drug Products

Sterile, Unpreserved, Pyrogen-free

Wet/wet
Large Vol Parenteral



Wet/dry
Small Vol Parenteral



Unit-of-use

Suspension

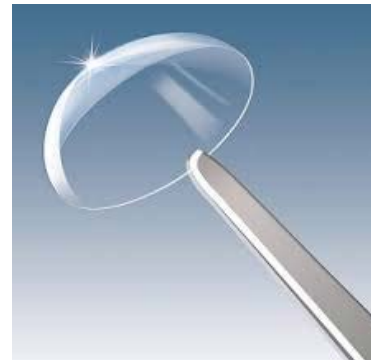


Biological Products

PROVISC® 1% high MW Sodium Hyaluronate
(human genetically engineered)
sterile, pyrogen-free



**Avitene™ Microfibrillar
Collagen Hemostat (MCH) -
1 Gram**



**ProShield® Collagen
Corneal Shield (bovine)
post-surgical bandage**



**Pork pancreatin
Enzymatic Cleaner
Effervescent Tablet**

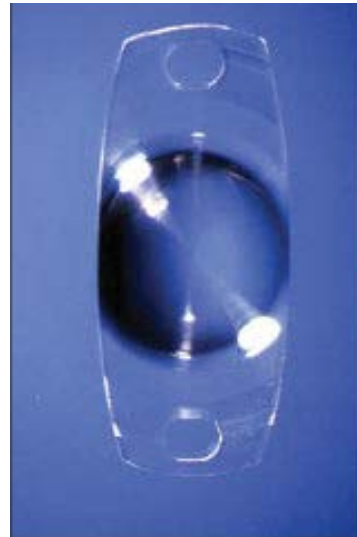
Medical Devices, sterile

Silikon® 1000
medical grade
silicone oil for
retinal
detachment



Medtronic i-Port Advance™
Injection Port

IOGEL® polyHEMA
Intraocular lens
(38% water) in BSS®
sterile, preservative-
free




OPTI-FREE®
Disinfection Platform
product line

Overarching Goal



Consider strategies to enhance the development of antimicrobial drugs **that change lives!**

Best ways to enhance antibacterial drug development?



Increase the quality of product candidates entering clinical trials.

Fund product candidates in development for **global distribution**.

Whose problem are you solving?



“Nearly nine in ten products fail within two years of release. Why? Because they don’t solve a customer *need*.”

Sheila Mello
Partner, Product Development Consulting Inc.
Customer Centric Product Definition

Decisionmakers: Who are you?



In order to make funding decisions that will result in successful products, you need to know where you are in the Industry Landscape (what type of product).

Who makes funding decisions?



Scientists?

Business people?

Definitions



Science is a method for obtaining knowledge about the laws of nature.

Purpose: Gain knowledge

Technology is the result of a design process; it begins with a need and ends with a solution--it is the product of human thought.

Purpose: Change the material environment

Experience Scope



During your career, have you developed:

A Product

A Technology

or

discovered the Laws of Nature?

WHAT are you selling?



Your Activities

Scientific Research

Technology Development

Product Development

What You Sell

Information

Component/Tool

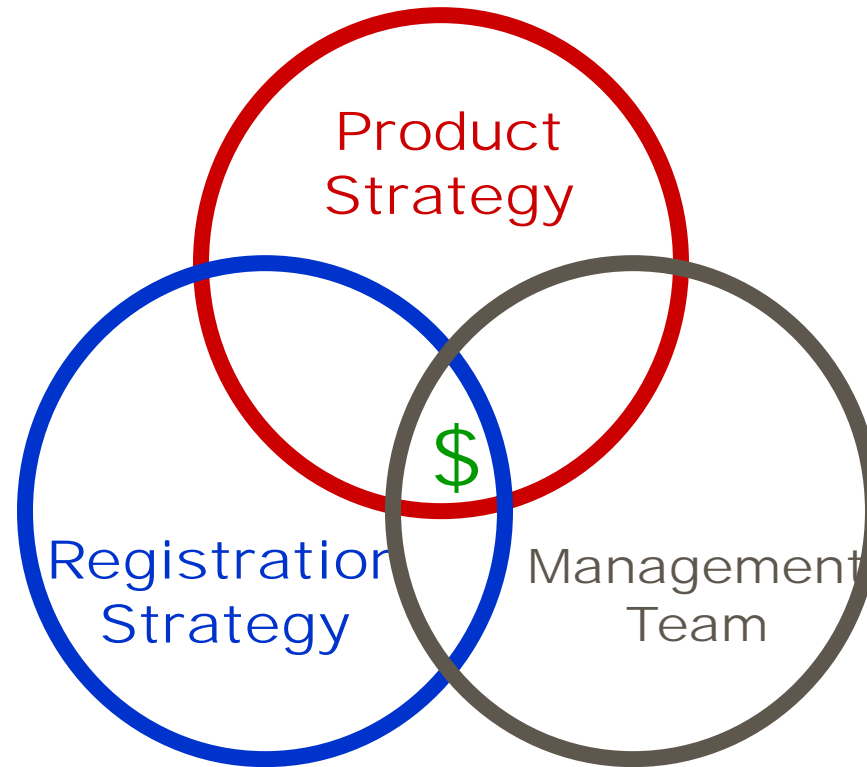
Finished Product

New Product Development is an Apprenticeship Discipline



- New Product Development **IS NOT** taught in school.
- The only place it is effectively and efficiently taught is inside **PROFITABLE** companies in the same industry.
- If you are not able to attract employees with appropriate experience, **OUTSOURCE!**

Complete Picture for NPD



*Well-defined products get funded,
developed, approved and change lives!*

Contact Info



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What is innovation?



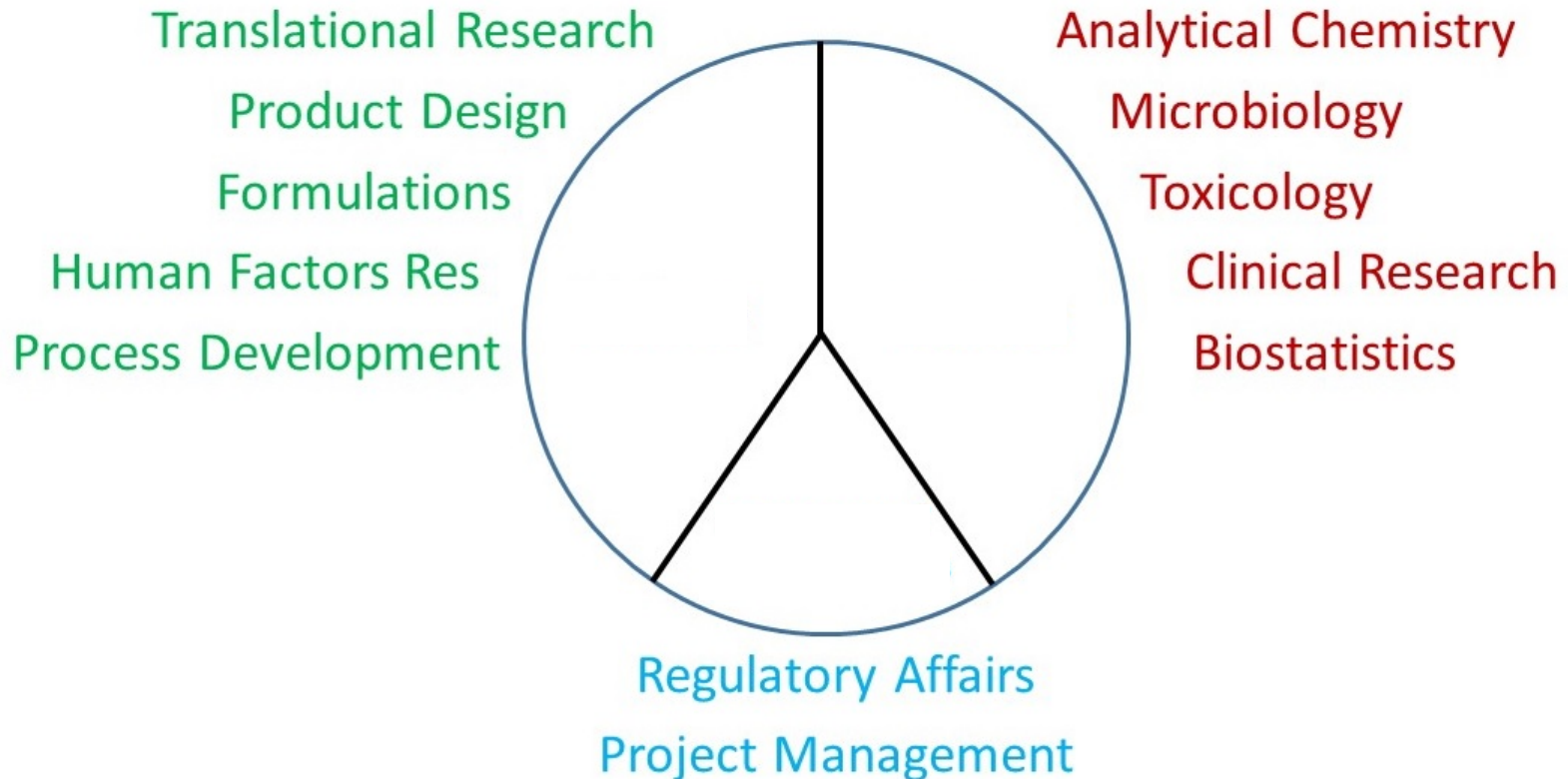
Invention—the process/result of finding novel ideas

Innovation—creating customer value

An innovation does not necessarily stem from an invention--it can result from combining existing technologies that result in creating new applications with high customer value.

Medical Product Development Team

Leader: Medical Specialty Director



Translational Research



“applies findings from scientific discovery to enhance human health and well-being.”

uses **clinically-relevant models** to turn Discovery results into usable product formats.

FailFastMPD™ Study Design

Example: contractor Mouse Allergic Asthma model

1: all samples prepared, masked, coded by Ovatrion personnel

2: each animal is handled precisely in the same way

Treatment Group	Negative Control	Positive Control	<u>Cortico-steroid</u>	s-IgY	n-IgY	<u>Other oral Tx</u>
IP injection	saline	saline	<u>Dex</u>	saline	saline	saline
Sensitization	saline	DME	DME	DME	DME	DME
Oral Gavage	saline	saline	saline	s-IgY	n-IgY	<u>other Tx</u>
Inhaled Challenge	DME	DME	DME	DME	DME	DME
....						

s-IgY: specific IgY (investigational material)

n-IgY: non-specific IgY (control)

IP: intraperitoneal injection for systemic treatment

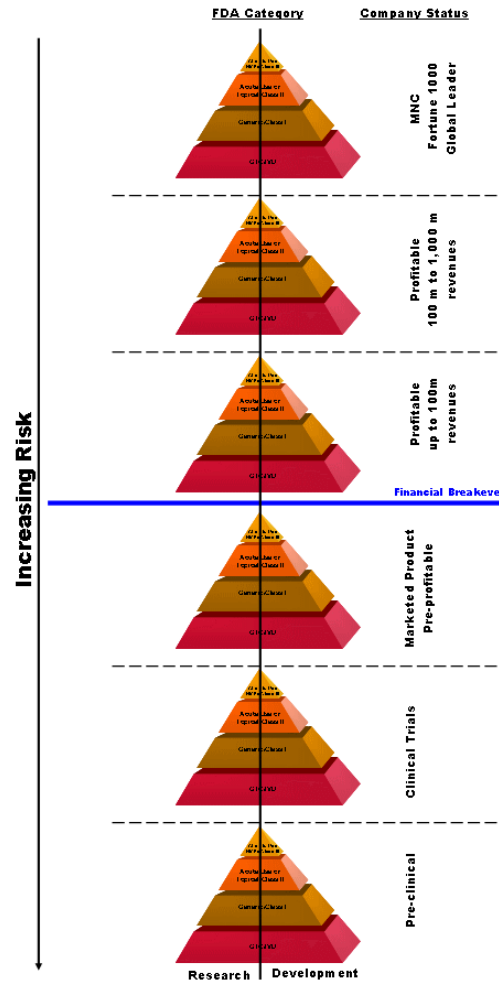
DME: dust mite extract

Dex: dexamethasone, used as systemic immunosuppressant

Industry Landscape™--MPD

Does Not Include: Foods, Cosmetics, Nutraceuticals, Veterinary Products, other Consumer Products, Chambers of Commerce, Economic Development, University Continuing Education, Real Estate Development, etc.				Finance									
	Level	Entity	5411, 5412, 4241 Business Services	325x, 335x Materials/ Equipment	Industry- specific Professional Services	New Product Development	Q/A	Manu- facturing	Marketing	4461 Sales	6211 Physicians	6211, Other HCS	
Employment	Executive												
	Contributors		Business Supplies/ Other	Accounting	Legal	IP Legal	Chemicals/ Biochemicals/ Equipment/ Research Tools	Physical Testing	Clinical Testing/Bios Processing				Customers
Education/training	Graduate/Postdoctoral	Univ/Gov Agency/ Gov Lab					NIH, NSF, DOD, DOE, NIST NASA, EPA, USDA, LANL, ORNL, Argonne, LLNL, AFRL, SRNL, LLL, Sandia, PNNL, Fermi NL						
	Basic Education	College/ University			Law School	Law School							Med School Internship Residency Fellowship
													Science/Engineering
													Science/Engineering
													Food & Drug Administration Customers
													Faculty
													Nursing Other

Training Company Stage



ExperienceMap™

	Level	Entity	5411, 5412, 4241 Business Services	325x, 335x Materials/ Equipment	Industry- specific Professional Services	New Product Development	Q/A	Manu- facturing	Marketing	4461 Sales	6211 Physicians	6211, Other HCS
Employment	Executive											
	Contributors		Business Supplies/ Other	Accounting	Legal	JF, Legal	Chemicals/ Biochemicals/Equipment/ Research, Tools	Physical Testing	Clinical Testing/Biostat	Processing		
Ed/Tr							Food & Drug Administration				Faculty	
							Science/Engineering				Med School	
							Science/Engineering				Science	Nursing
											Engineering	Other

ExperienceMap™--CLL

	Level	Entity	5411, 5412, 4241 Business Services	325x, 335x Materials/ Equipment	Industry- specific Professional Services	New Product Development	Q/A	Manu- facturing	Marketing	4461 Sales	6211 Physicians	6211, Other HCS
Employment	Executive											
	Contributors		Business Supplies/ Other	Accounting	Legal		IP/ Legat	Chemicals/ Biotechnicals/Equipment/ Research Tools	Physical Testing	Clinical Testing/Biostat	Processing	
Ed/Tr							Food & Drug Administration				Faculty	
							Science/Engineering				Med School	
							Science/Engineering				Science Engineering	Nursing Other