

RJR Consulting, Inc.



Advancing prevention technologies for sexual and reproductive health

Session 4: Integrating Multi-Purpose SRH Technologies Into Prevention Strategies

Bob Russell

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President--Biography

Bob Russell

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RJR Consulting, Inc. has offices in Columbus, OH, Washington, DC and Brussels, Belgium. The company assists the pharmaceutical, medical device and biotech industries in understanding and complying with International Regulations affecting compliance, new product development, manufacturing and quality assurance.

Bob has a BS / MS in Chemistry.

He has 28 years of past industry experience as a CMC specialist, R&D Director and Global Director of Regulatory Affairs for Merion Merrill Dow and Cordis-Dow.

Company Profile

Pharmaceutical, Medical Devices, Biotechnology, Combination Products Consulting [NA, EU, Japan, Latin America]

- ✧ Authorized Rep. / Legal Rep. in EU
- ✧ Strategy Development
- ✧ Clinical Trial Set-Up
- ✧ Marketing Authorizations
- ✧ License Renewals
- ✧ Variations / Amendment Filings
- ✧ Manufacturing Authorizations
- ✧ Drug Master Files
- ✧ Certified Medical Writing
- ✧ CRO Management & Selection
- ✧ Inspection Assistance / Pre-Audits
- ✧ Government / Agency Regulatory Affairs
- ✧ Training
- ✧ International Regulatory Surveillance Updating: NA, EU, Asia-Pacific

SRH Technology and Resulting Products

- Pathway from Research - Development - Licensing / Use
- Where is it developed / designed?
- Where is it clinically proven?
- Where will it be utilized?

=> Linkage of Product Development & Global Regulatory Compliance

Linkage of Product Development & Regulatory Compliance

- Design / CMC - Clinical Trial - Licensing - Use

- Product is regulated based upon how it is classified
- Product is classified based on its primary intended “action”
- Primary action is driven from Product Claims
- Path of Licensing / Registration drastically different

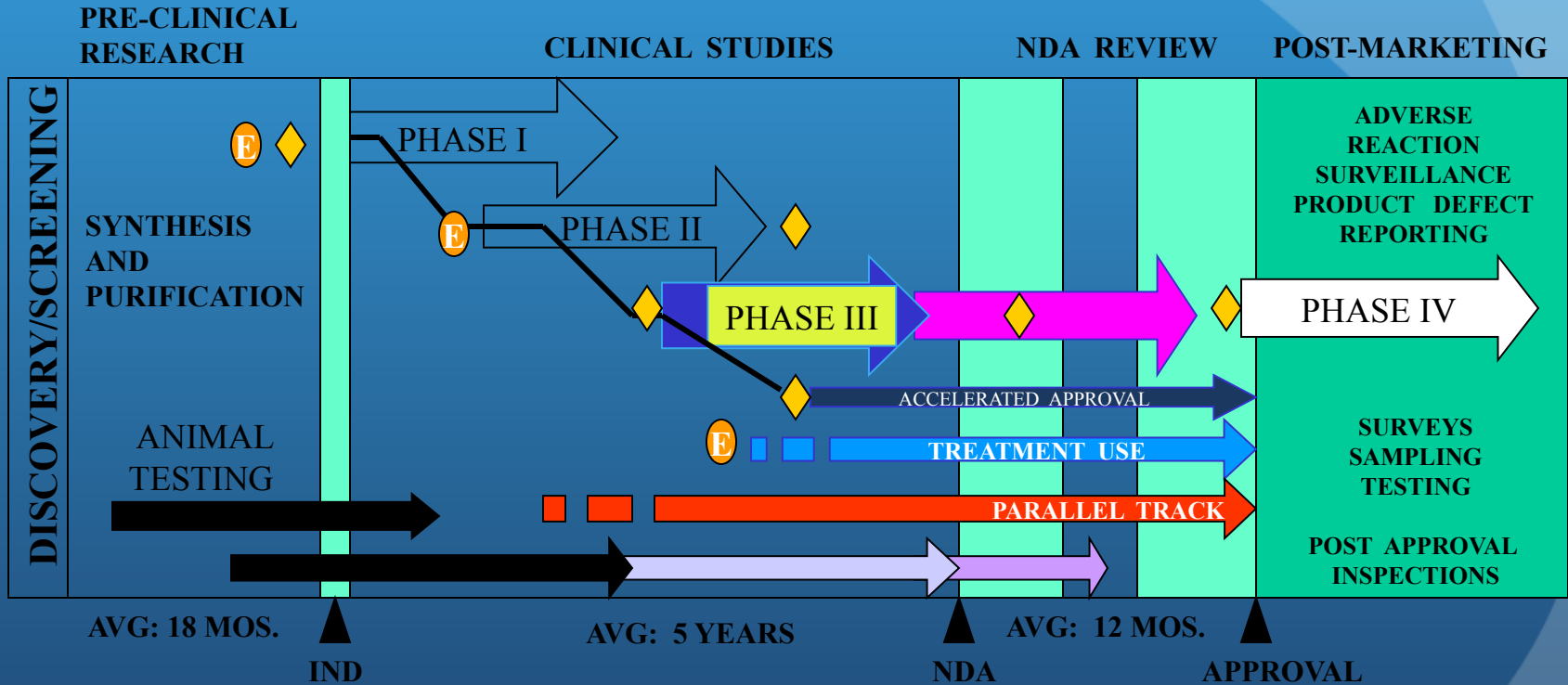
Medicinal Product or

Medical Device

Combination Product

Biologic

FDA IND Development



FDA TIME

INDUSTRY TIME

FDA & INDUSTRY TIME

SPONSOR/FDA MEETINGS ENCOURAGED

ACCELERATED REVIEW:

SUBPART E

ACCELERATED APPROVAL

EXPANDED ACCESS:

TREATMENT USE

PARALLEL TRACK

Risk - Reward Balance for Regulators

- Should take into account Acuteness of Disease
- Should take into account Stage of Development
 - entering Clinical Trials
 - entering commercial use / distribution
- What do we reasonably need to know to advance innovation without considerable patient risk