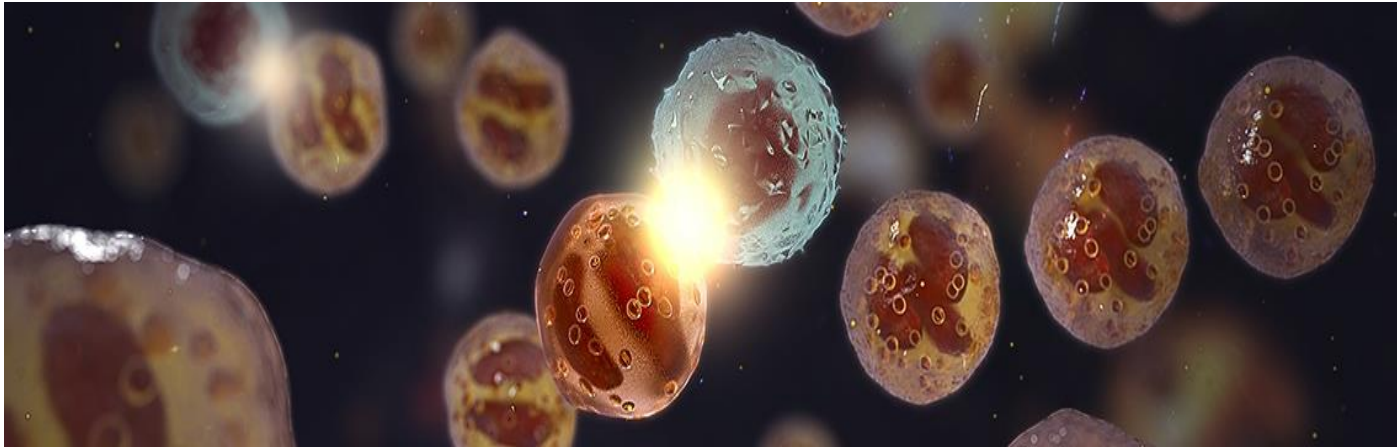


The Future of Strategic Thinking in Pharma Manufacturing

Harish Aditham

Continuous Improvement Manager, AstraZeneca Operations, Australia

24 Jul 2017



Where are we today?

MONEY & MARKETS

Airline CEO predicts a future where 'we will pay you to fly'

BENJAMIN ZHANG
JUL 15, 2017, 9:12 PM

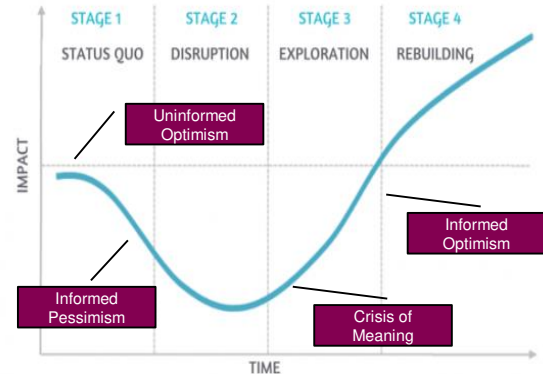
f FACEBOOK t TWITTER ↑ REDDIT in LINKEDIN ✉ EMAIL



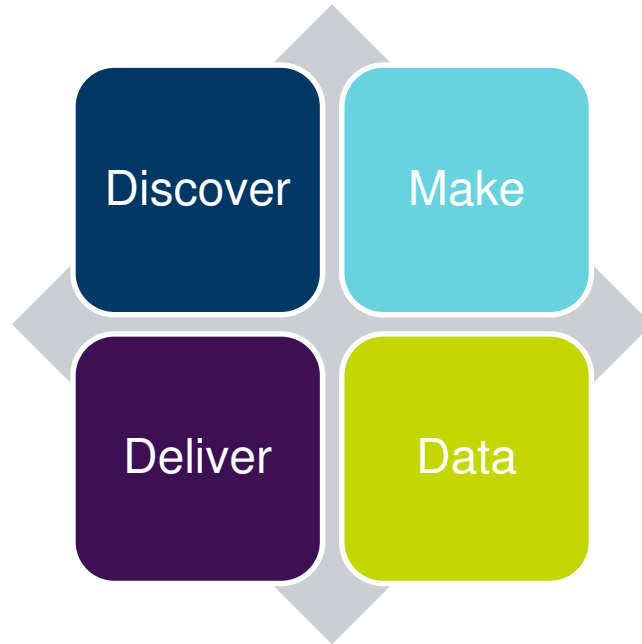
Inflection and related buzzwords

Product \longrightarrow Service

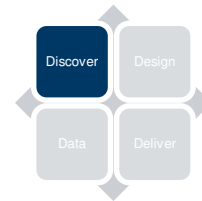
- Industry 4.0
- Continuous Manufacturing
- Quality By Design
- Specialty Pharma
- Novel Drug Delivery
- Open Innovation
- Agile supply



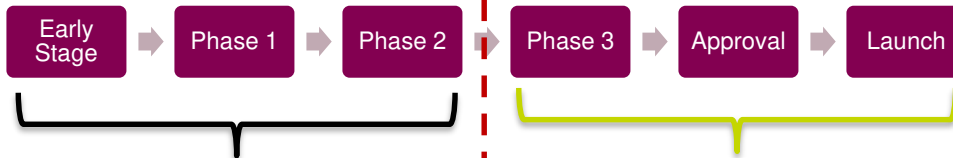
A Framework for Dialogue



The Era of Specialty Pharma and Operations as Leverage



More molecules
Targeted pathways



Smaller volumes
First to market

Cross industry collaboration,
focused therapeutic areas, bolt on
acquisitions, open innovation

Greater collaboration with
Manufacturing, novel drug delivery,
launch optimisation

Challenges

- Smaller Volumes
- Drug delivery complexity

Impact on Operations

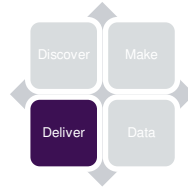
Opportunities

- Industry 4.0
- Operations as investment centre



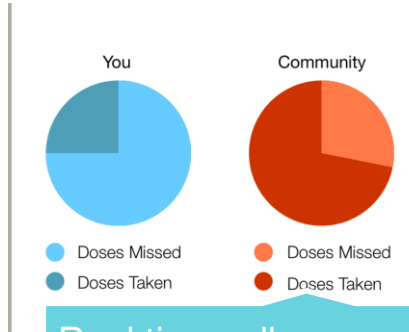
Delivering value and access

Data will be a unique advantage for pharma companies



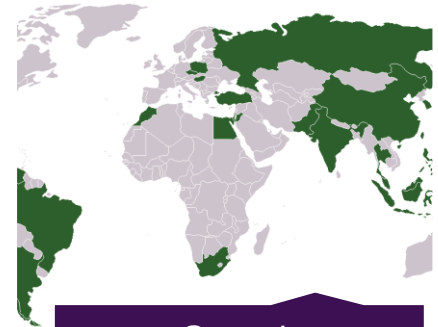
Multi-channel data

59% of patients use a health app



Real time adherence and event monitoring

Average drug adherence ~ 50%



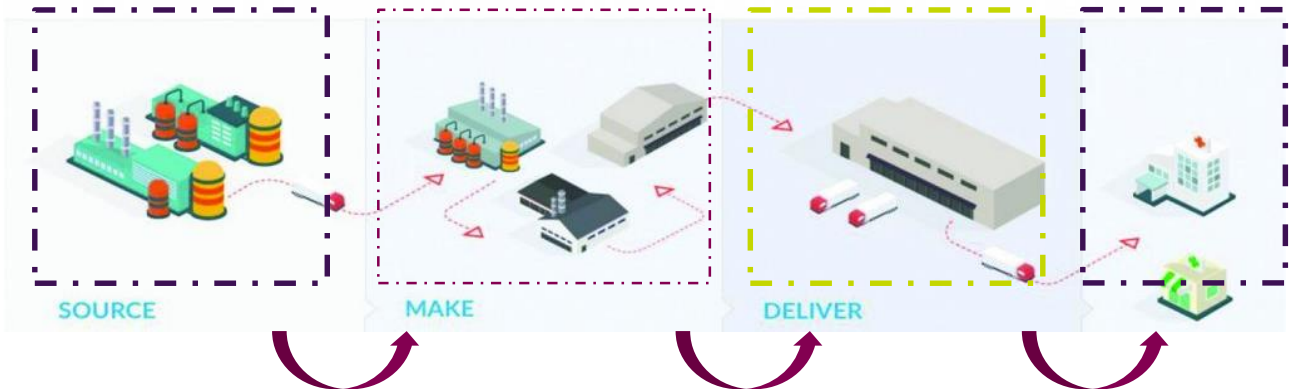
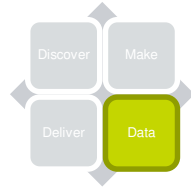
Growth Differentiation

Emerging markets sales ~ 30%



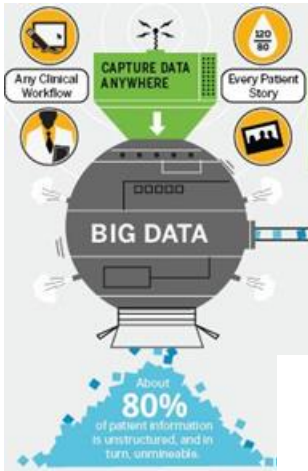
The Data Ocean Lakes

- Profusion on data being generated at every node in increasingly complex supply chain
- Manual transfer of data between nodes of differing parties
- In a world with more data how do we see and validate relevant data? What about Data Integrity?

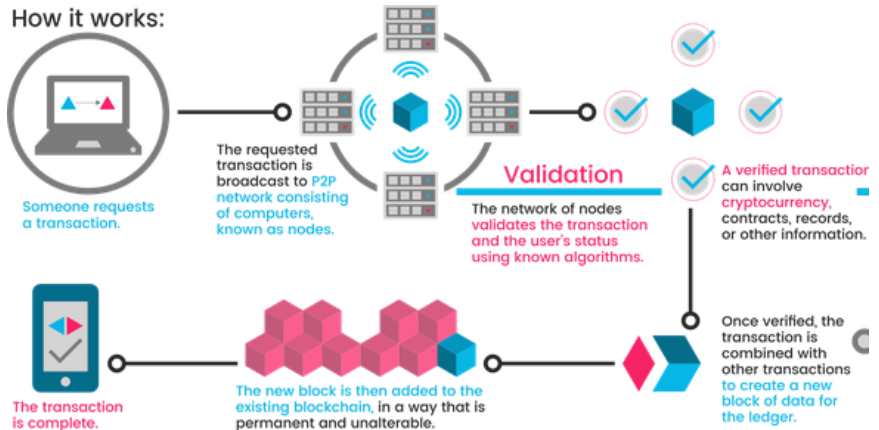


The Next Step in Data Integrity

An indelible, unalterable, contemporaneous record – without the need for an ERP change



How it works:



The Manufacturing Revolution

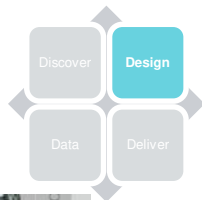
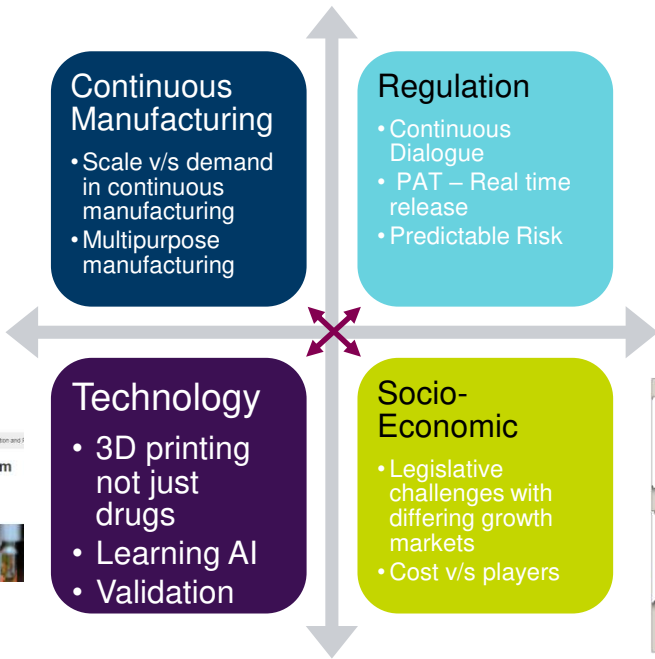


Continuous Manufacturing

- Scale v/s demand in continuous manufacturing
- Multipurpose manufacturing

Regulation

- Continuous Dialogue
- PAT – Real time release
- Predictable Risk



About FDA

Home > About FDA > FDA Organization > Office of Medical Products and Tobacco > About the Center for Drug Evaluation and Research

About the Center for Drug Evaluation and Research

CDER Offices and Divisions

Drug Safety Oversight Board

Jobs at the Center for Drug Evaluation and Research (CDER)

Meeting Presentations (CDER)

CDER Exclusivity Board

Emerging Technology Program

Background

CDER's Office of Pharmaceutical Quality created the Emerging Technology Program (ETP) in a vision on Modernizing Pharmaceutical Manufacturing to Improve Drug Quality, Ensuring a Safe and Adequate Supply of Drugs to provide the adoption of innovative approaches to pharmaceutical product design and manufacturing. The

Brazil

REC: 0000000000
SN: 01234567890123
LOT: 012345
EXP: DEC 2007

US/Europe

GTIN: 00312345000000
SN: 01234567890123
LOT: 012345
EXP: DEC 2007

China eCode

中国药品电子监管码

sketch map

12345 67890 12345 67890

电话查询: 9 5 0 0 1 1 1 1
短信查询: 106695001111
网站查询: www.drugadmin.com

Saudi Arabia

GTIN: 0035067656
EXP: 12-2015
LOT: 123456



So where is Pharma Manufacturing heading towards?



Commercialisation
– Scale - Supply
as leverage for
Big Pharma



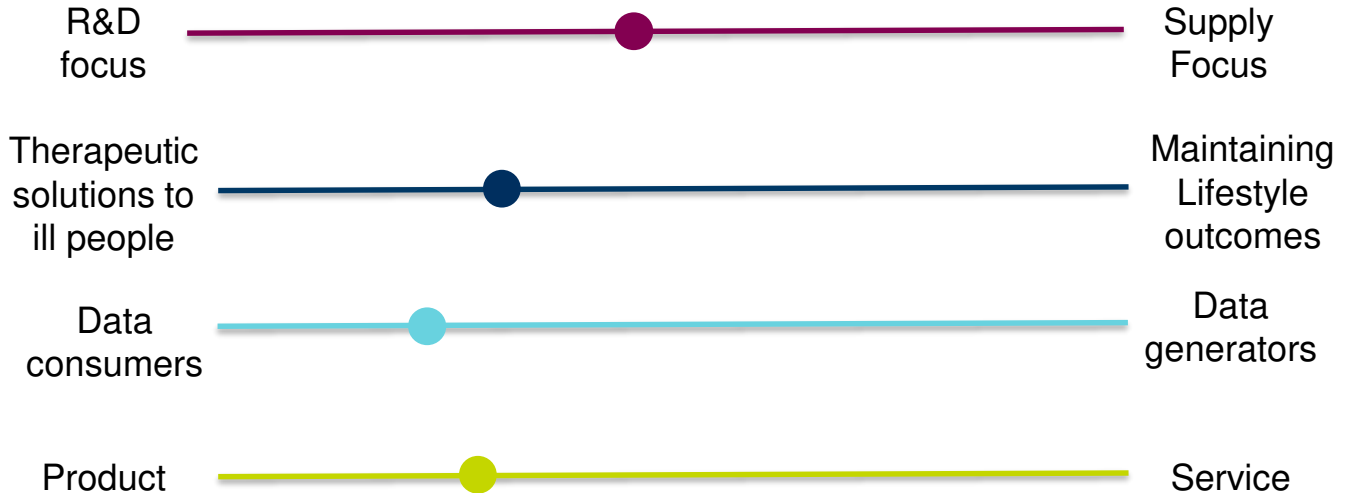
Increase in data
intensity



A search for
golden mean of
technology v/s
regulation



An Industry in Flux – Change the new constant



Confidentiality Notice

This file is private and may contain confidential and proprietary information. If you have received this file in error, please notify us and remove it from your system and note that you must not copy, distribute or take any action in reliance on it. Any unauthorized use or disclosure of the contents of this file is not permitted and may be unlawful. AstraZeneca PLC, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, CB2 0AA, UK, T: +44(0)203 749 5000, www.astrazeneca.com

