PMINJ Chapter
Symposium - 06 May 2019

NEW JERSEY CHAPTER

Launching a Digital Start-up in a Highly Regulated Environment

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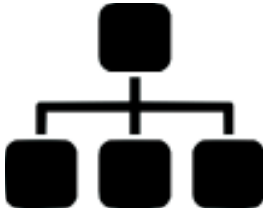
Acronyms (Pfizer, Medical Device industry, ISO, Regulations)

AE	Adverse Event
BT	Pfizer's Information and Information systems delivering business value
BU	Business Unit
ISO	International Organization for Standardization (ISO) is an independent, non-governmental international organization with a membership of 161 national standards bodies
ISO 13485:2016	Quality management systems first published in 1996 specific to Medical Device design, development and deployment. Revised in 2016.
LM	Legal Manufacturer
MD	Medical Device
PC	Product complaints
PGS	Pfizer Global Supply
QMS	Quality Management System
SMD	Software as a Medical Device

The Start of the Journey

Pfizer Software Medical Devices

- Rules
- Regulations
- Laws



Our Journey Continues

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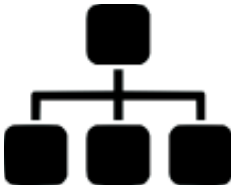

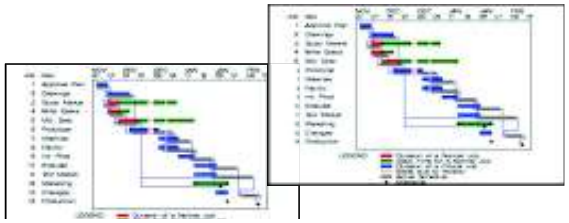

- Rules
- Regulations
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Legal Manufacturer (LM)

Virtual Approach to a Legal Manufacturer

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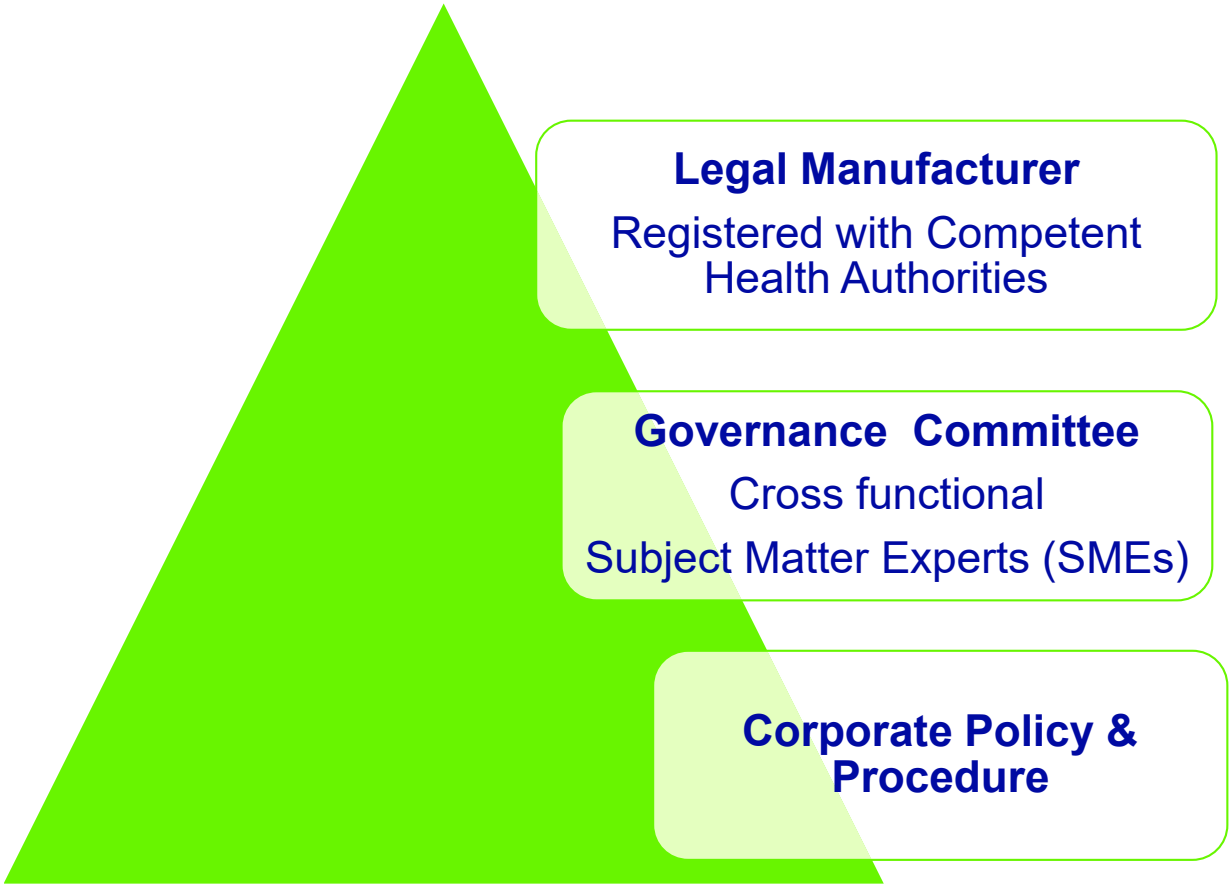
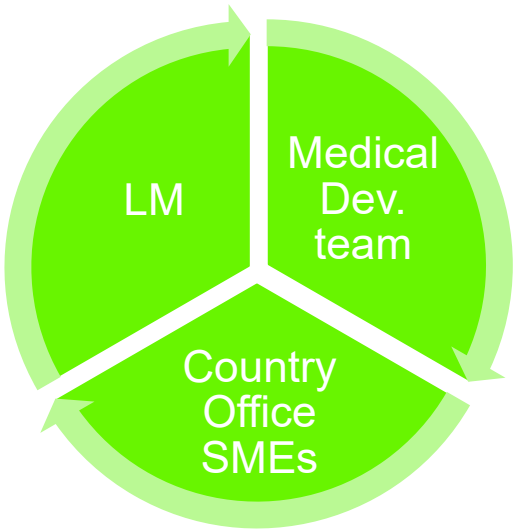
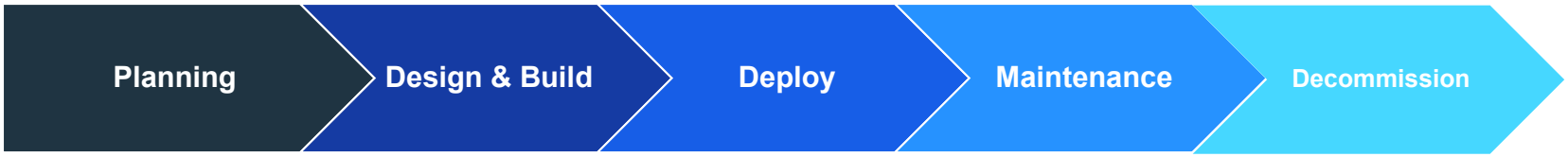


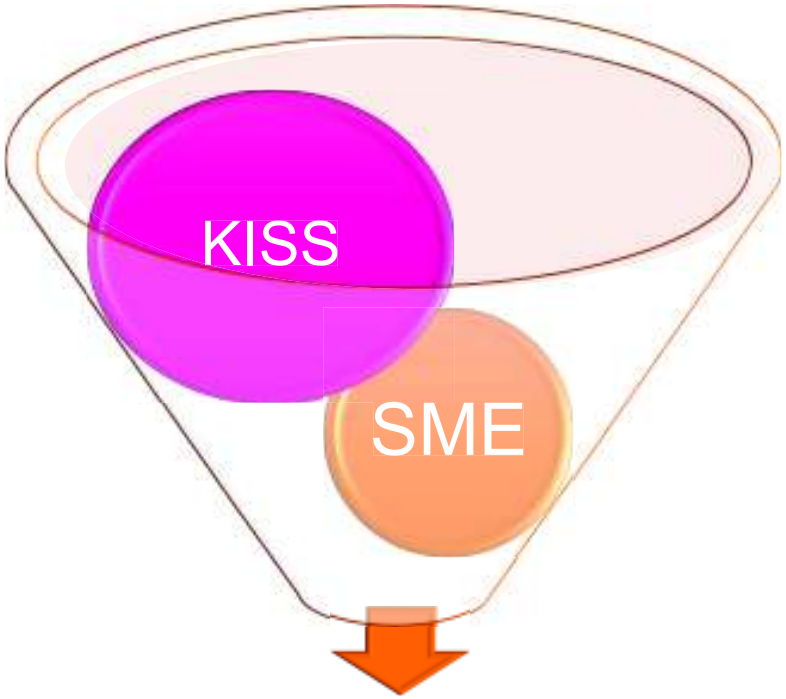
Working Relationship, Process, Tools



Project Management tools
• Project Charter
• Product Scope (in & out)
• Organization planning
• Human Resource Planning & Execution
• Risk Identification, Analysis & Control
• Quality Plan - Regulatory, SDLC, Design Control
• Activities definition, duration and sequencing
• Deliverable with RACI and Dependencies
• Decision to close project / deploy digital product



Lessons Learned Planning

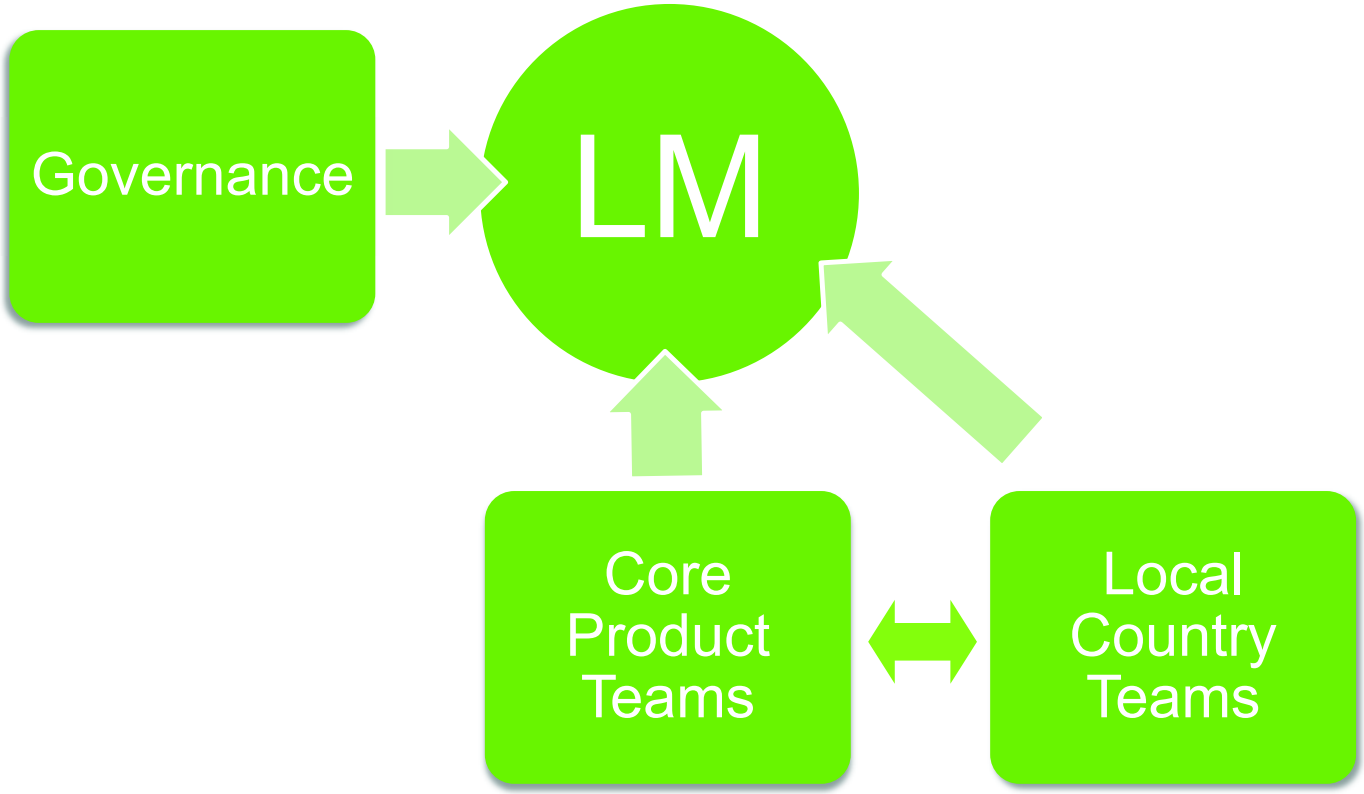


Empowered Subject Matter Experts

Keep it Simple & Streamlined

Focus on Compliance & Continuous Improvement

Lessons Learned Execution



Footnotes

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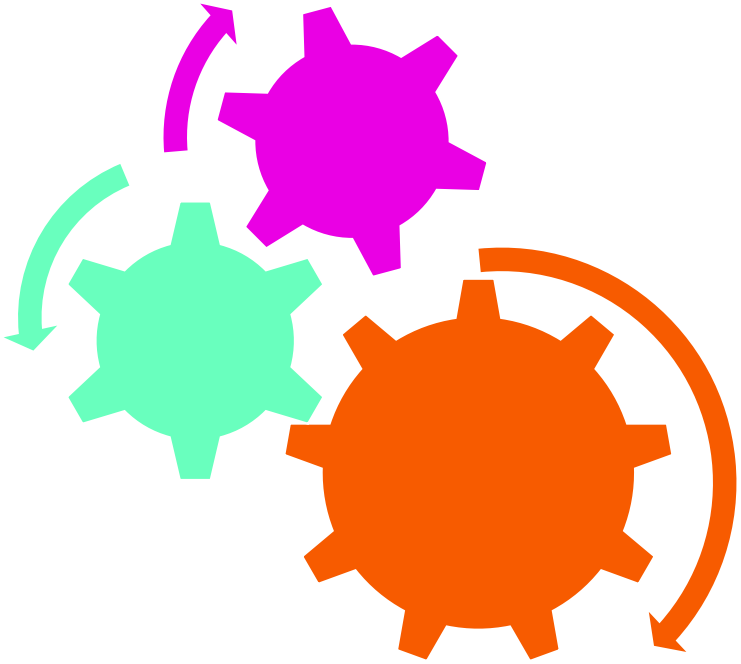
#	Reference
1	FDA clears non-prescription Type 2 diabetes digital therapeutic ... https://www.healthdatamanagement.com/.../fda-clears-non-prescription-type-2-diabete... **FDA clears non-prescription Type 2 diabetes digital therapeutic**. By. Greg Slabodkin. Published.**January 26 2017**, 2:24pm EST.
2	Telemedicine Carts - American Well https://www.americanwell.com/telemedicine-equipment/carts/ The **American Well 760** Telemedicine **Cart** is an **FDA Class** I **registered** ... an **FDA Class** I **registered** medical **device** used to **bring** remote **specialists** to the point .
3	Apple Watch Series 4 is first consumer device to receive FDA ... https://appleinsider.com/.../apple-watch-series-4-is-first-consumer-device-to-receive-fda-...
4	Why ZIO - iRhythm Technologies https://www.irhythmtech.com/patients/why-zio The **Zio monitor** can be comfortably worn for **up to 14 days**. Holter **monitors** can be worn for 24 to 48 hours, limiting the time to record any irregular **heart** rhythms you may have. **Zio** is able to capture data for the 51% of patients who have their first symptom-triggered arrhythmia after 48 hours.

Thank you

Q&A



For any questions, comments, please contact me at

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