CFA INSTITUTE WEBINAR:

From Breakdown to Opportunities: Medtech powers rapid recovery from COVID-19

Tuesday, 19 May 2020
2:30pm – 3:30pm HKT (GMT+8)

CFA Institute

SPEAKER

Jack Wong
Founder of Asia Regulatory Professional Association (ARPA)

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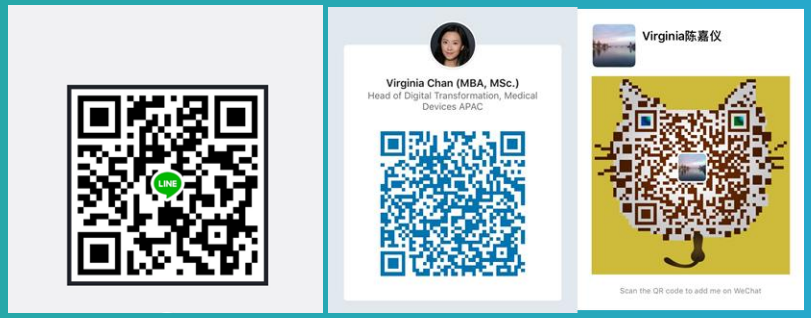
Speaker Profile

- Over 18 years of medical devices and digital health industry experience in global and APAC leadership
- Head of Marketing & Sales Development (APAC) at the world's leading dental implant company Straumann and received "Frost & Sullivan" Award
- Global Product Development Lead in Germany and APAC Marketing Director at Dentsply Sirona (No. 1 dental company)
- Chair of Digital Regulatory at Asia Regulatory Professional Association

Virginia Chan

MBA, MSc. (Information Systems Management)
Head of Digital Transformation, Medical Devices Industry, APAC



From Breakdown to Opportunities : MedTech powers rapid Recovery from COVID-19

Embrace the new normal and learn how medical technology industry speeds up life-saving for preventive measures and treatments

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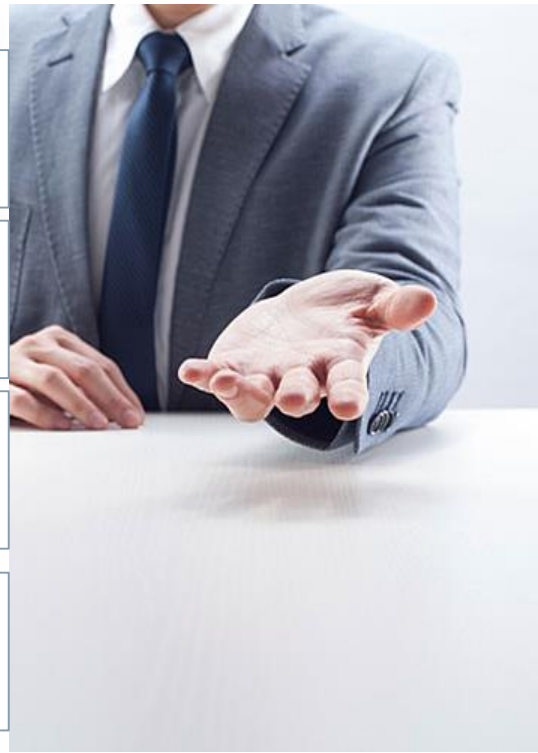
1. **Industry 4.0 : digitalization to accelerate innovation & ramp up production**
2. Digital Health as the new normal using IoT (Case study)
3. #Regulators ease rules to speed up breakthrough in drugs and vaccines
4. Implication for investors and the public at large



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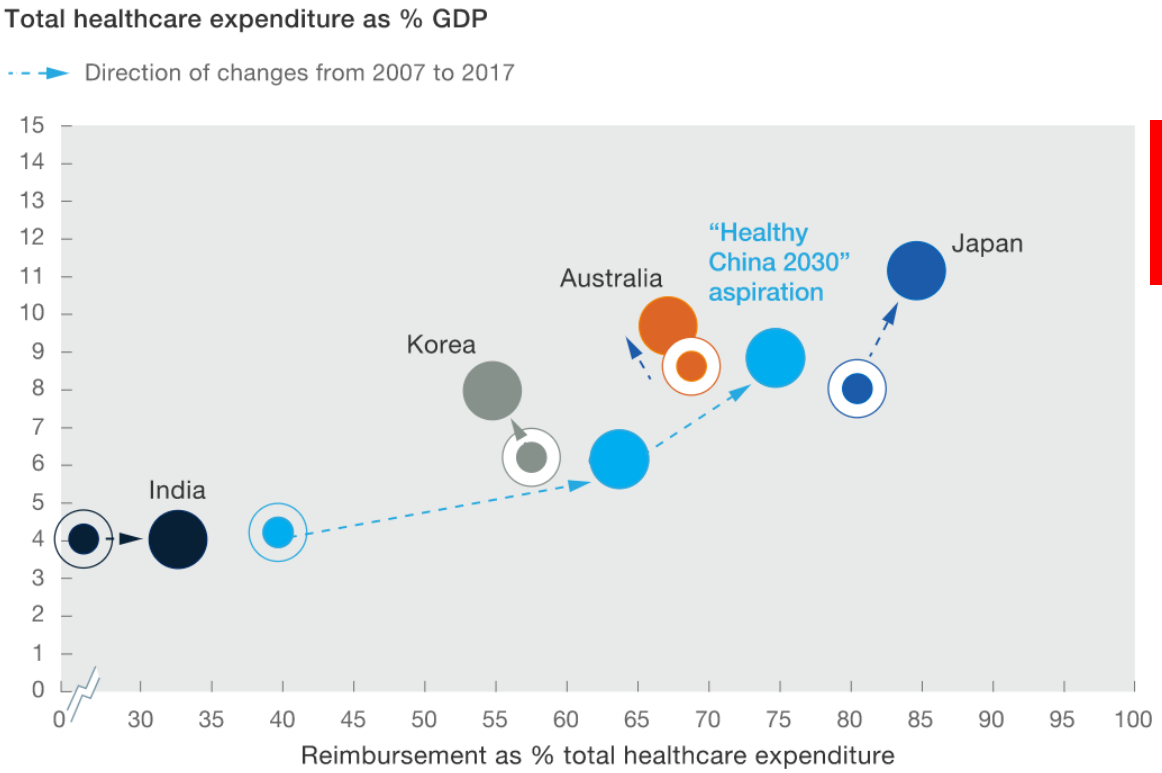
COVID-19 accelerates Megatrends towards digital transformation of Medical Devices Industry

Healthcare Security is National Security
COVID-19 accelerates digitalization in healthcare industry



US
>20% GDP
>11,000USD

McKinsey&Company | **Source:** BMI Research; press search

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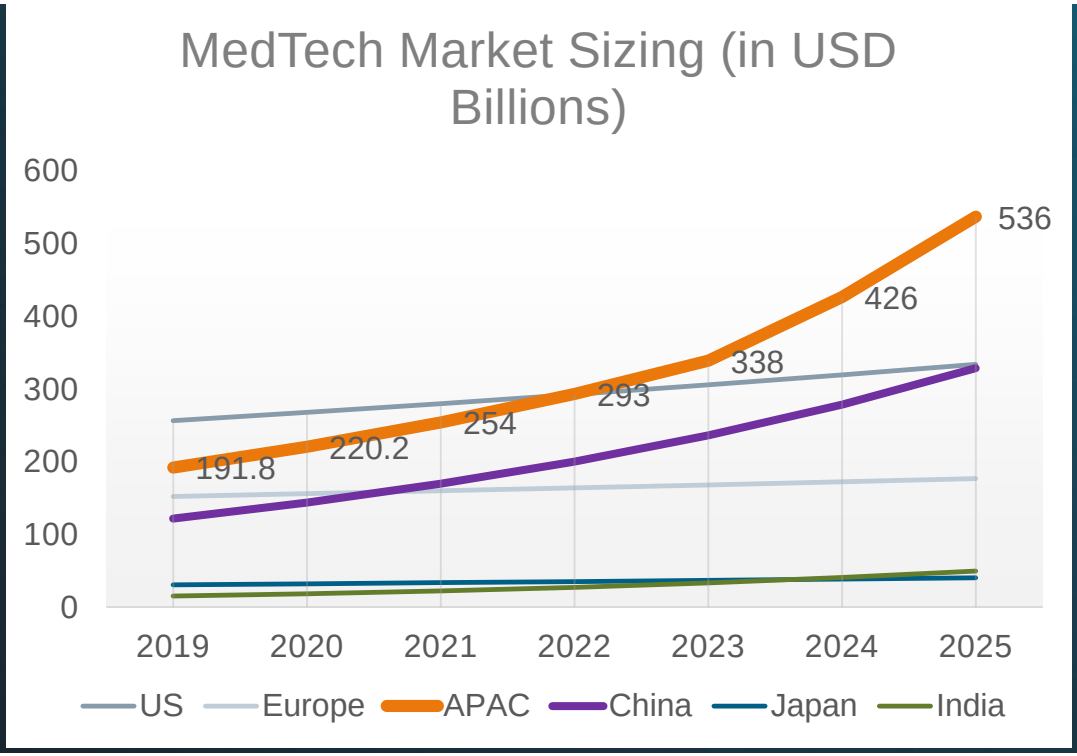
USD500Billions Global Medical Devices Market in 2019

Aging Population & Emerging Markets Accelerate growth



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#Fight COVID-19 : Critical moment to Support production ramp-up and regulatory approval of Medical Supplies

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Wave 1 : Protective Gear

- 40% PPE
- 2X gowns
- 3X N95
- 6X surgical mask

Wave 2 : Life Support & Test Kits

- Ventilator
- Test Kits
- Dialysis
- Diagnostic equipment

Wave 3 : Drug & Vaccine

- Overall supply of MedTech
- Drug and Vaccine

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Industry 4.0 to accelerate
innovation and ramp up production

Accelerate Innovation through production with Digital Twin (Physical to Virtual World with Data)

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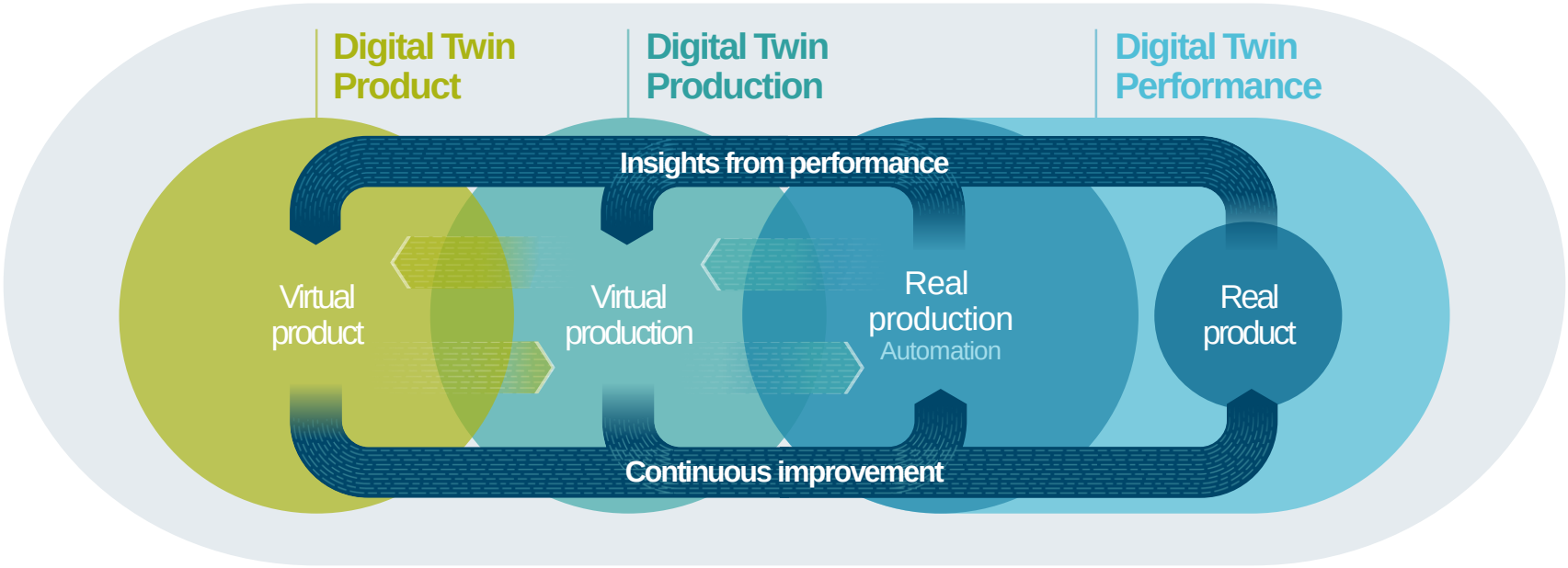

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Virtual Reality – Catheter and Lung Model Facilitate Training & Education

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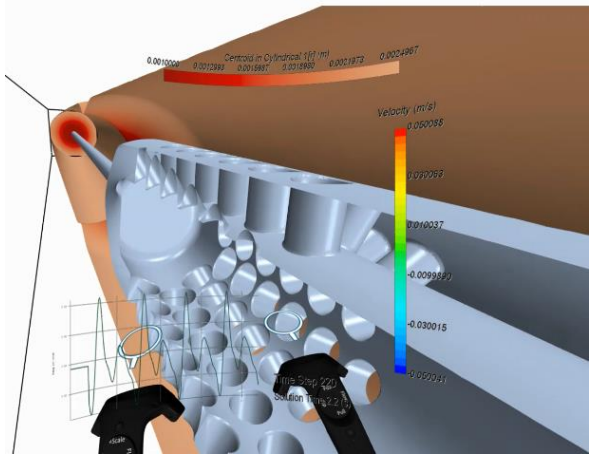

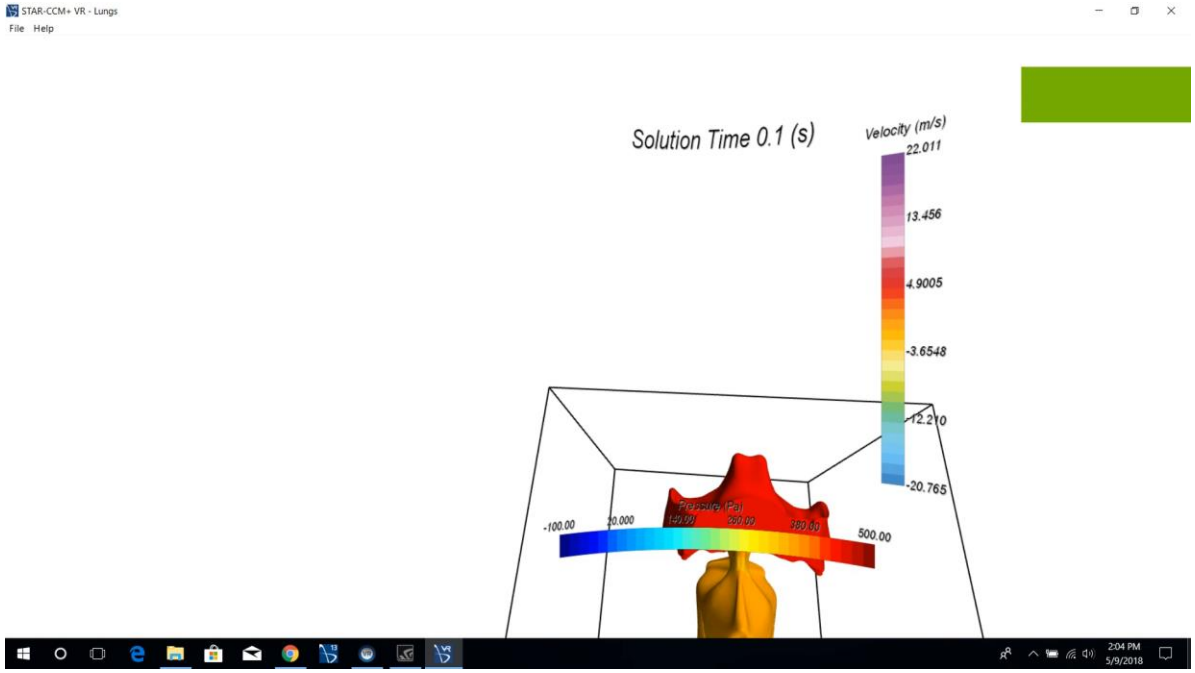

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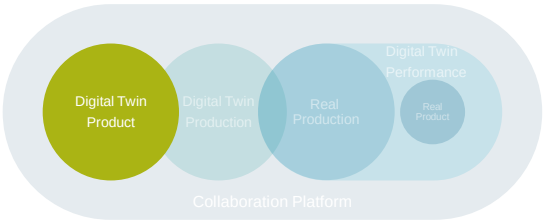
Digital Twin Product

Unrestricted © 3



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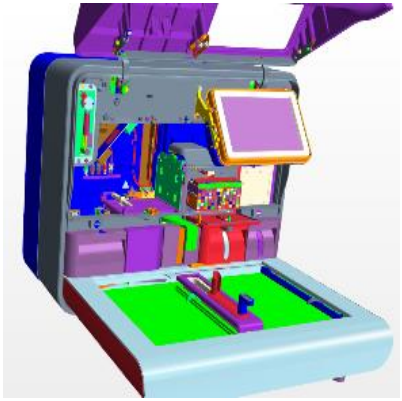
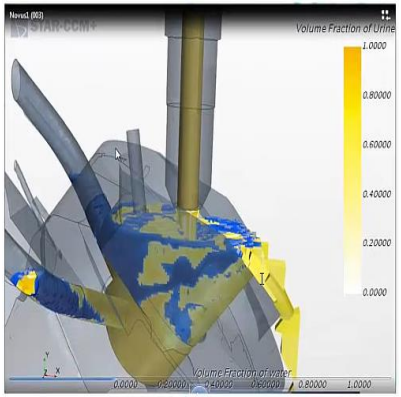
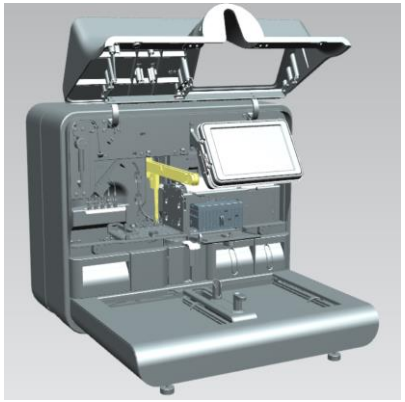
Product Design & Operation Simulation

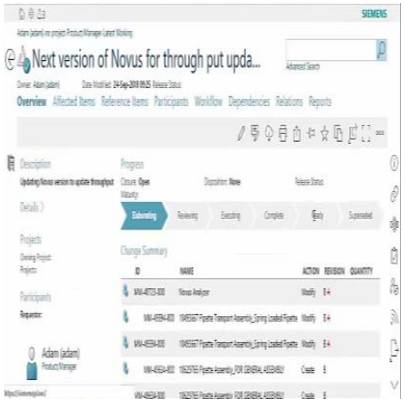


Design Optimization

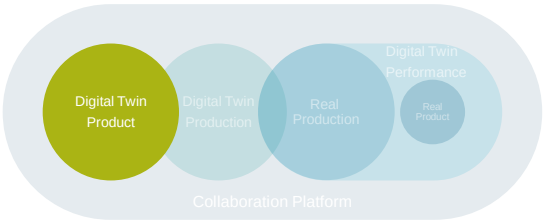




Multi-Discipline Design Update



Change Package Release



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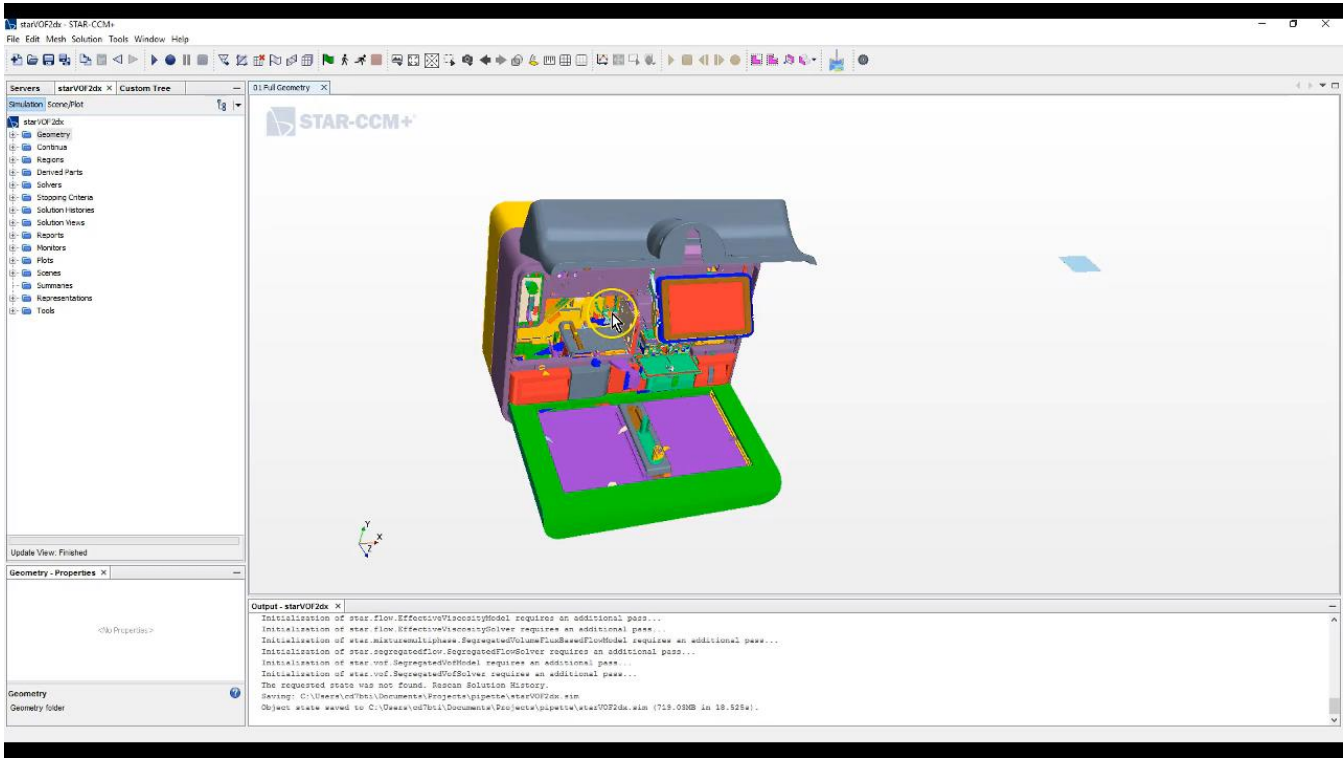
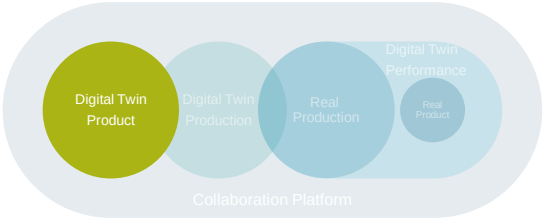
Design Exploration & Optimization

Fewer design cycles required; greater understanding / insight obtained through digital prototype





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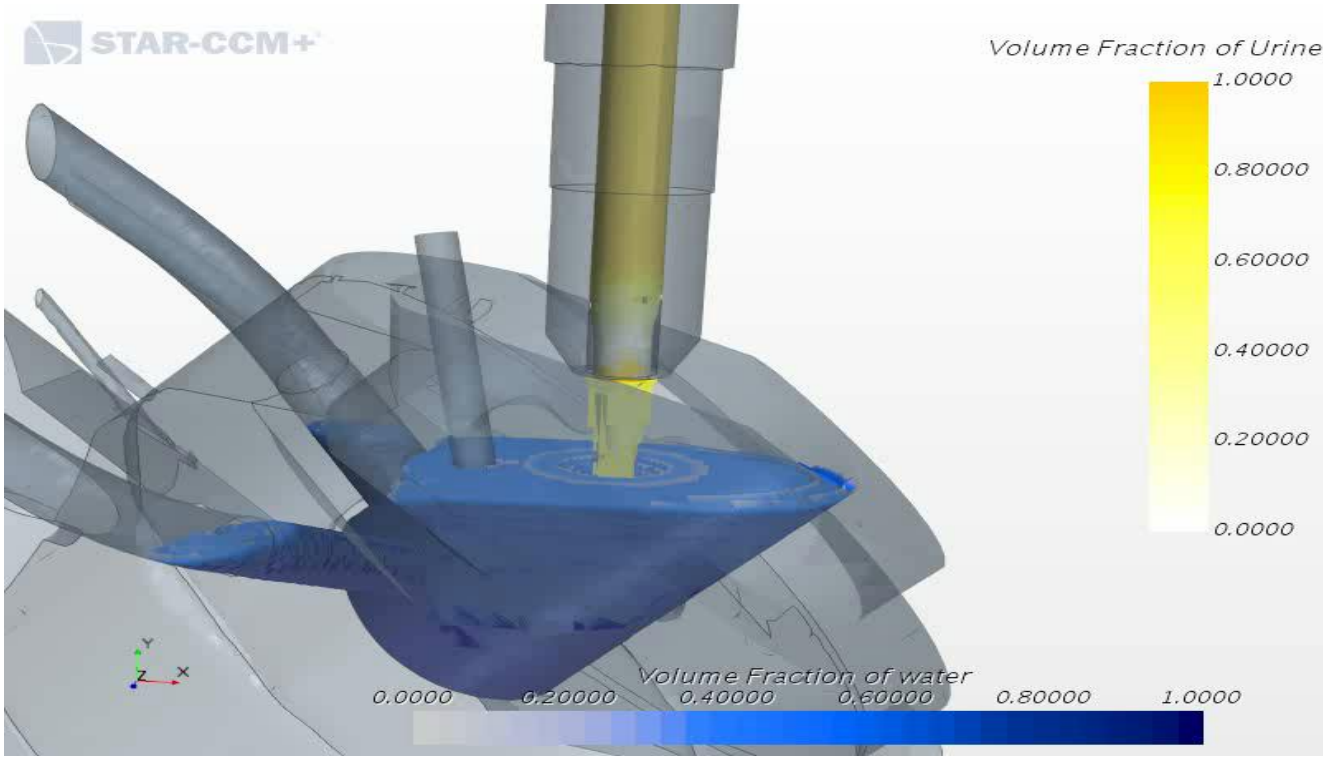
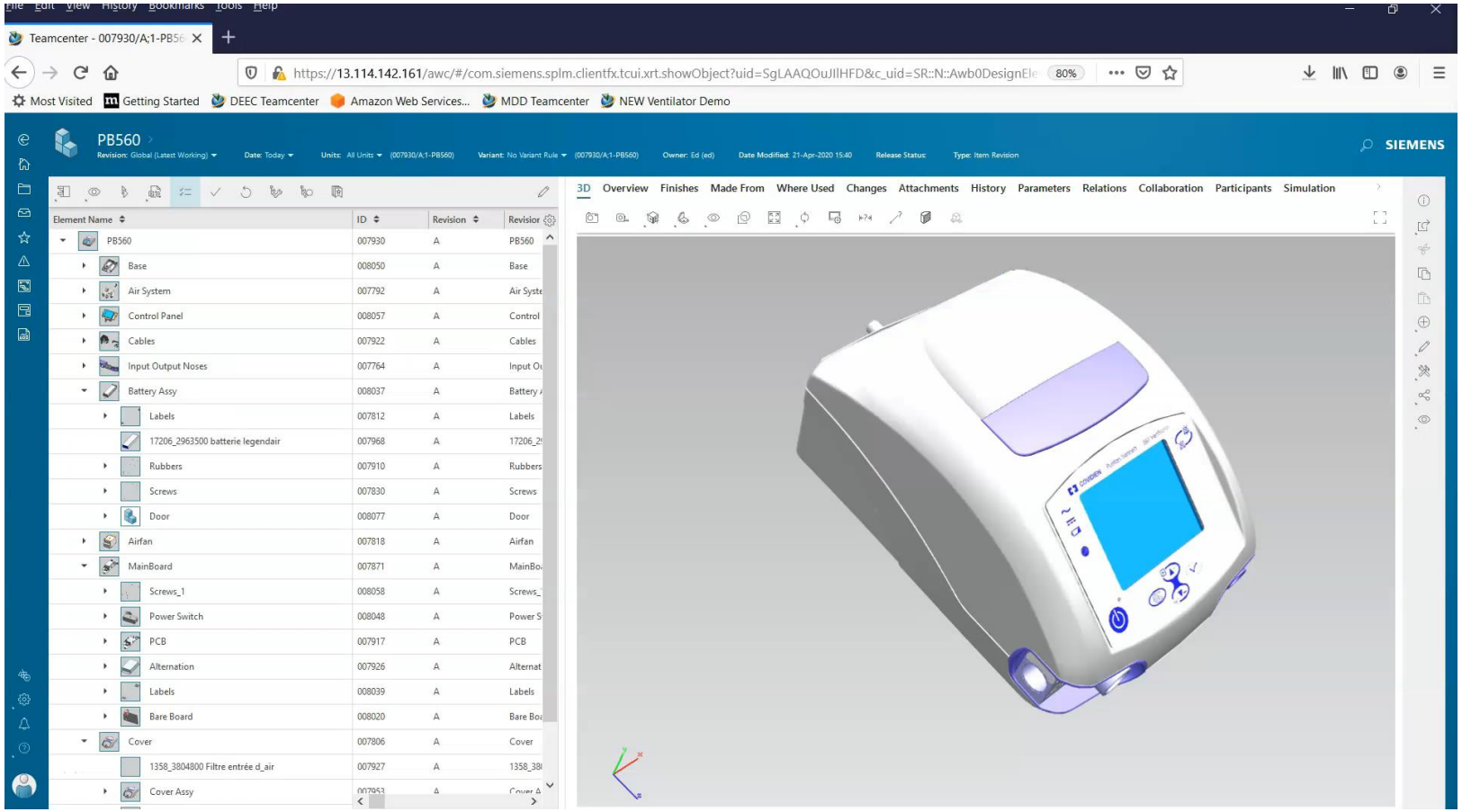
Fluid Flow Analysis

Optimize fluid flow for throughput while meeting sample quality requirements



Ventilator – 4 weeks from design files to production



l Twin
duct

Digital Twin
Production
with
social distancing

Re
produ

Social Distancing and Remote Digital Factory for business continuity

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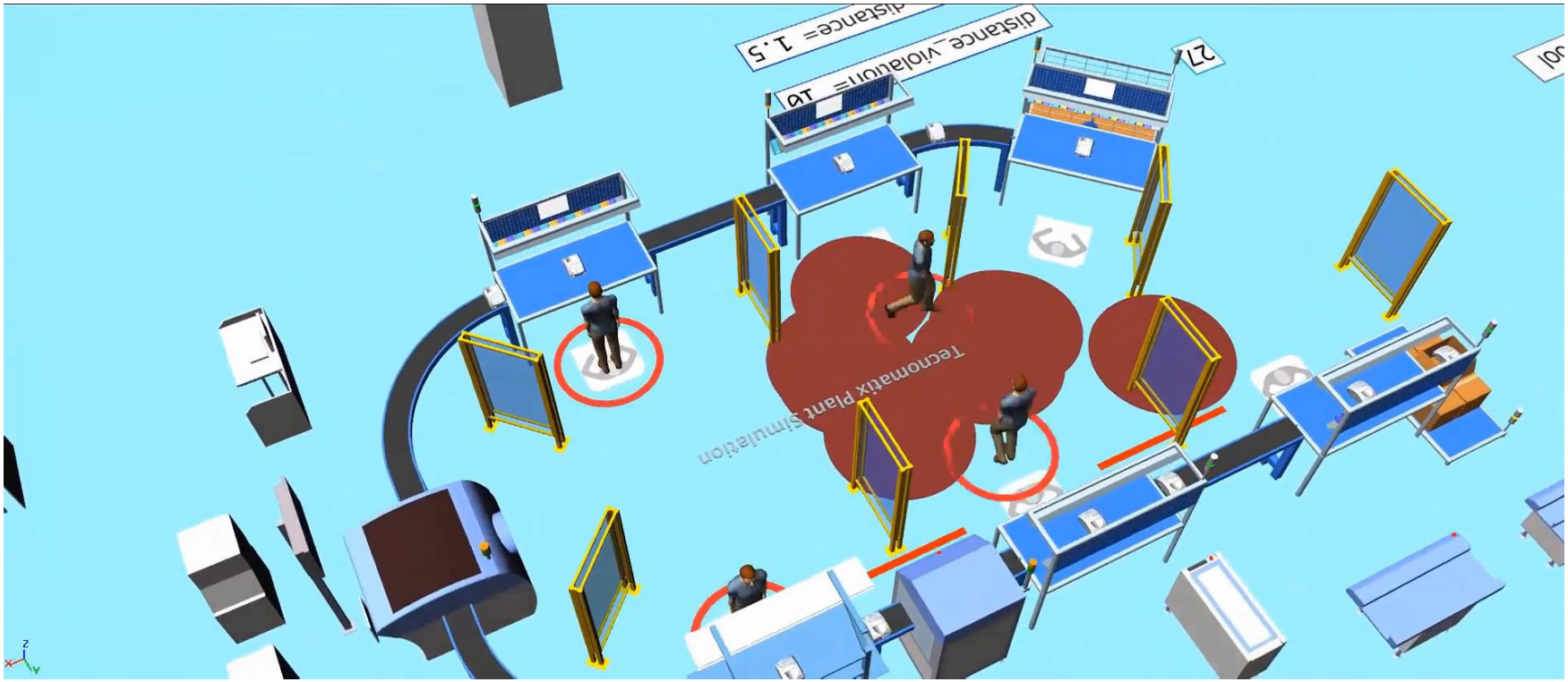

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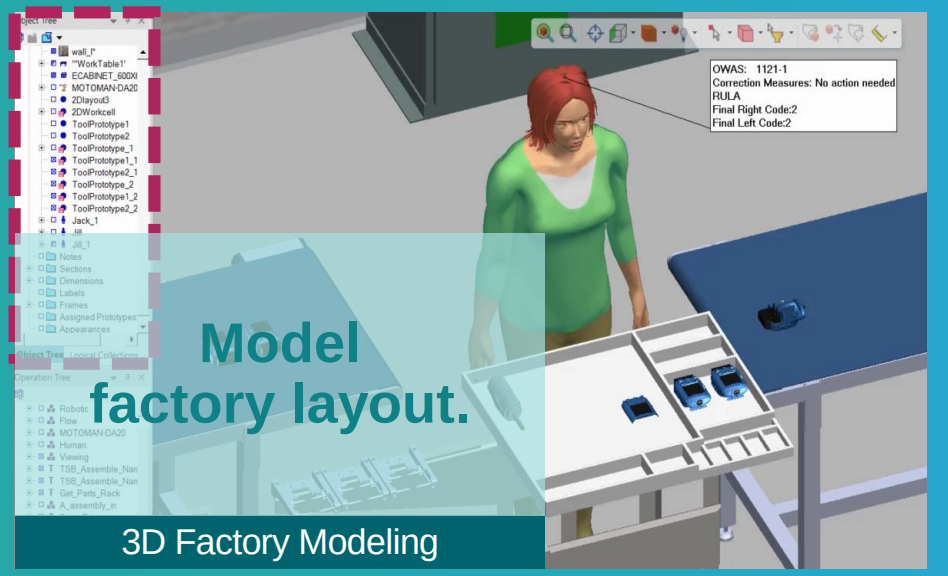
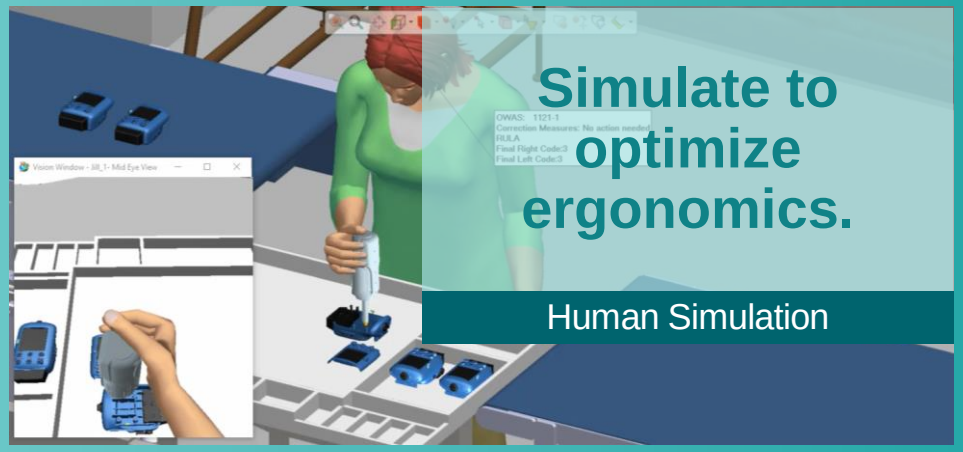
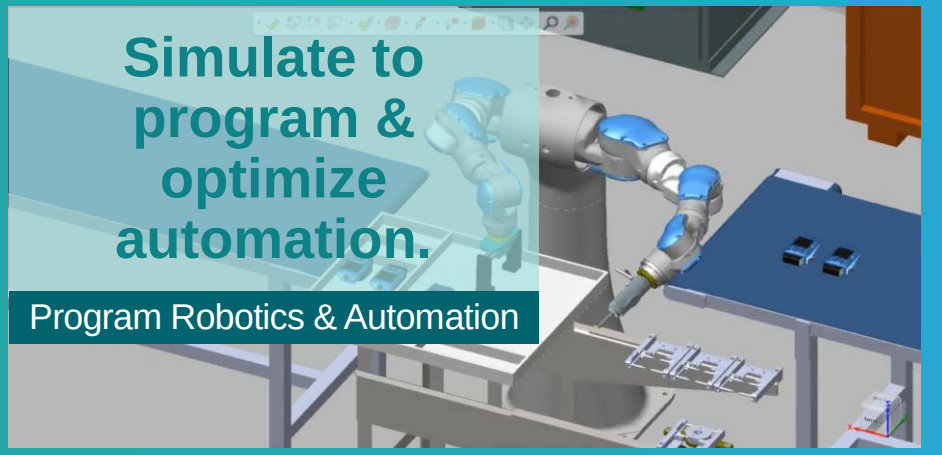
Author mBOM & mBOP.
Mfg Process Modeling


OWAS: 1121-1
Correction Measures: No action needed
RULA
Final Right Code:2
Final Left Code:2
Model factory layout.
3D Factory Modeling


Simulate to optimize ergonomics.
Human Simulation


Simulate to program & optimize automation.
Program Robotics & Automation

Additive Manufacturing : Design new product and support parts production

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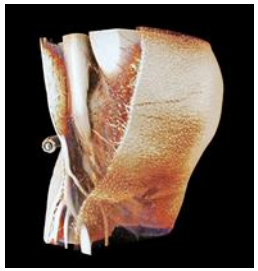

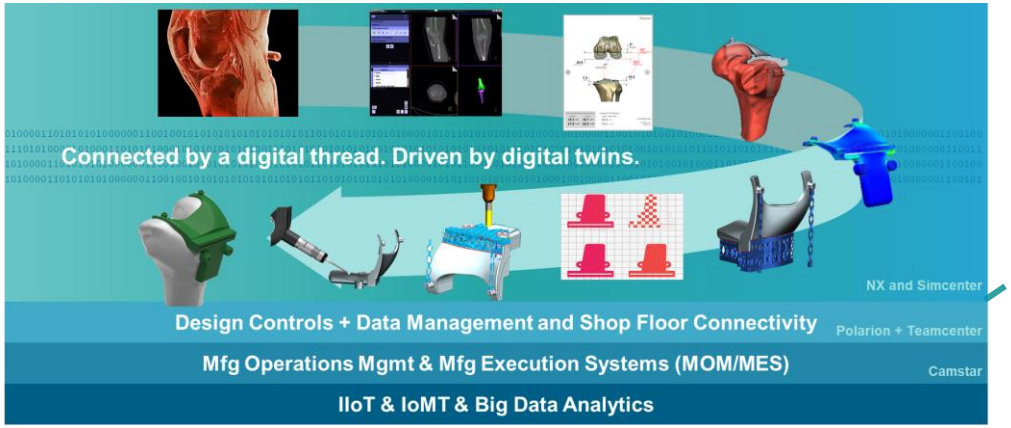

Design & optimization	Build Plan and Printing
Scan & segment	Define build Plan
Plan surgery	Analyze part for print
Design instruments and / or implants	Build Preparation
Verify design	Generate print job file
Verify printability	3D Printing
	Post Processing & Inspection
Product Digital Twin	Production Digital Twin

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Digital Health as the new normal :
Telemedicine, AI, robotic and home monitoring for contactless healthcare

Digital health innovation
From home monitoring, telemedicine to hospitals

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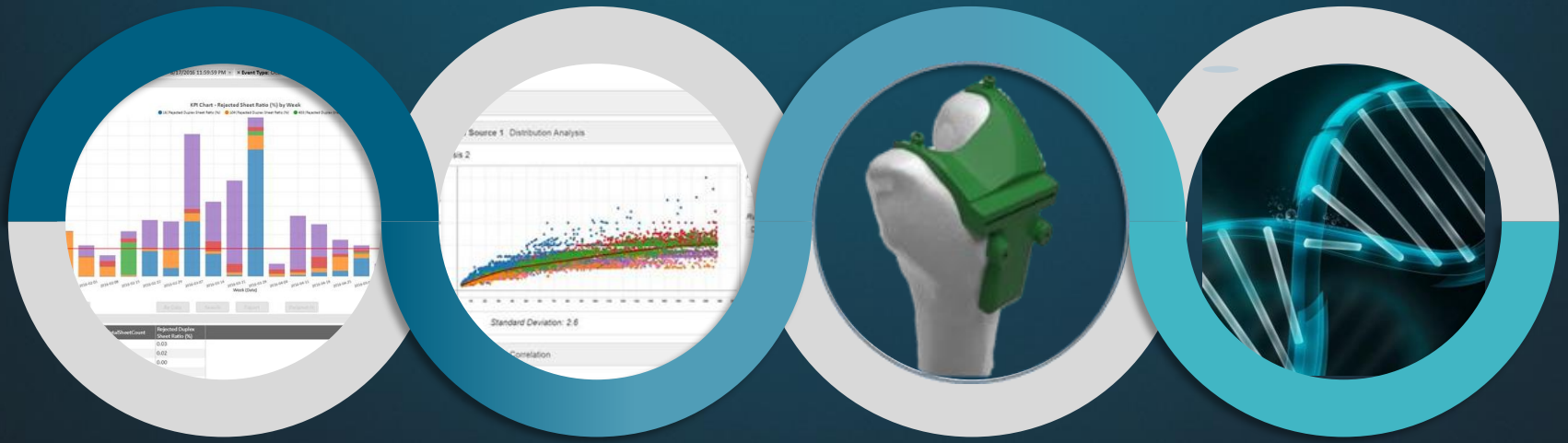
Create value-based healthcare with patient-centric business model using IoT and AI

Preventive

Predictive

Personalized

Precision Medicine



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2021

USD136

BILLION

Digital health

Telemedicine grow >100% after COVID-19

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Digitalization in MedTech industry advances healthcare and creates investor value

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3-5%
COGS reduction

3-15%
EBITA* increase on R&D digitalization

30-50%
Shorter time-to-market

39 of 40 Top Medical Device companies globally gain benefits of digitalization

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From Purpose to Impact :
Great investment for the Greater Good

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HOW **FINANCE, DIGITALIZATION AND REGULATORY** CAN LEVERAGE OPPORTUNITIES IN MEDTECH

JACK WONG

19 MAY 2020

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Topics

1. COVID-19 challenges to opportunities (**6D**)
2. How to prepare for this (**Partnership**)
   - ❑ What is Regulatory
   - ❑ What is ARPA
   - ❑ Let's acquire the Regulatory Power
3. **Next steps**

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COVID-19 - Challenges

Challenges – 6 D

-Debt
-Deflation
-Deficit
-Currency Devaluation
-De-globalization
-Digital Disruption

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COVID-19 - Opportunities

Challenges – 6 D

-Debt
-Deflation
-Deficit
-Currency Devaluation
-De-globalization
-Digital Disruption

New income and New supplies

See MedTech solid demand (Both Internal and External)

Leverage Finance, Digitalization and Regulatory partners

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What is Regulatory in MedTech

Every step has regulations!

1. Clinical trial approval
2. Product registration approval
3. Importation regulation
4. Local testing requirement
5. Promotional claims regulation
6. Adverse event reporting requirement etc

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PRODUCT TEST DATA
RISKS TO HEALTH
FLUID RESISTANCE
FILTRATION EFFICIENCY
DIFFERENTIAL PRESSURE (DELTA-P) TEST
FLAMMABILITY TESTING

MANUFACTURING QUALIFICATION
ISO 13485 STANDARD

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What are the regulations

Regulations are changing

Regulation interpretation is an art

Your Regulatory Partner - ARPA

ARPA

Asia Regulatory Professional Association

About ARPA

- **Asia Regulatory Professional Association**
- Established 1 Jan 2010
- 4600+ members
- ARPA aims to **raise the standard and social recognition** of Regulatory Professionals as part of Healthcare team.

Asia Regulatory Professional Association - RAPanel

Jack.Wong@ARPAEdu.com

www.ARPAEdu.com

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Education

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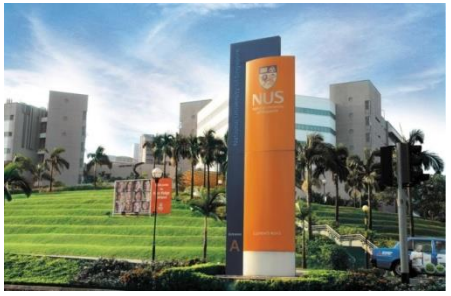
Education - Universities



NTUT

TOHOKU UNIVERSITY

香 港 大 學
THE UNIVERSITY OF HONG KONG

NANYANG TECHNOLOGICAL UNIVERSITY

NUS National University of Singapore

THE UNIVERSITY OF SYDNEY

PEKING UNIVERSITY 1898

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Education - ThaiFDA

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Education - TaiwanFDA

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Education – Malaysia MDA (MEDICAL DEVICE AUTHORITY)

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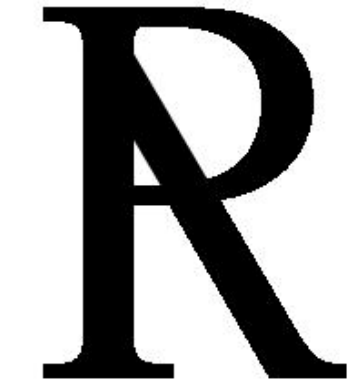
Education – Vietnam



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Publication

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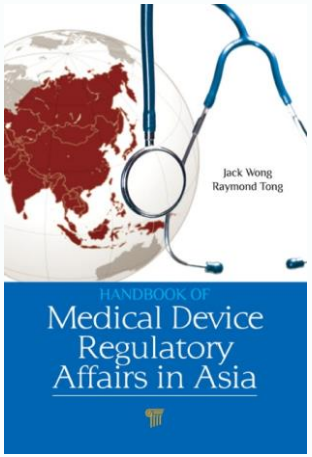
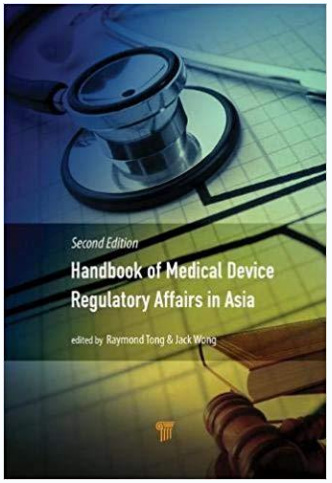
Publications

Regulatory Textbook

- To develop the professional, the very first Asia Regulatory textbook was developed
- Name of book: **Handbook of Medical Device Regulatory Affairs in Asia**
- We got support and writers from the following organisations to write the book (AHWP, WHO, US FDA, EU, Japan PMDA etc.)





What is medical device?

Definition

Medical Device

any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

diagnosis, prevention, monitoring, treatment or alleviation of disease

diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap

investigation, replacement or modification of the anatomy or of a physiological process

control of conception

Does not achieve principal action by pharmacological process, immunological means but may be assisted in its function by such means

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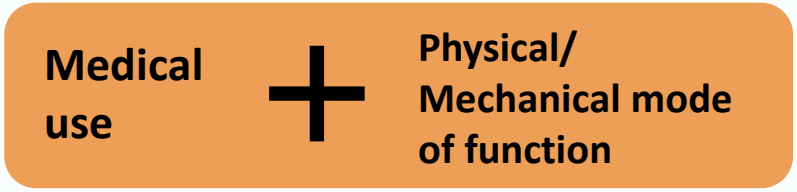
Medical Device



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Medical Device

Medical use	+	**Physical/ Mechanical mode of function**
diagnosis, prevention, monitoring, treatment or alleviation of disease		Does not achieve principal action by pharmacological process, immunological means

Questions

Alcohol wipes is classified as medical device?

Questions
Alcohol wipes is classified as medical device?

Answer: What do you want?

- Pharmaceutical: clean wound (pharmacological action with human body)
- Medical device: clean surgical instruments
- Household product: clean floor (no medical use)

Medical use + **Physical/ Mechanical mode of function**

Questions
Alcohol wipes is classified as medical device?

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Answer: What do you want?

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Medical use + **Physical/ Mechanical mode of function**

Classification and Launch pathways

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Questions

Vaccine is drug, Syringe is device. Prefilled Vaccine syringe is drug or device?

Questions

Vaccine is drug, Syringe is device. Prefilled Vaccine syringe is drug or device?

Answer: Drug

- Primary function is Vaccine and hence the combined product follow Vaccine classification i.e. drug
- 1 registration vs 2 registrations

Questions

Vaccine is drug, Syringe is device. Prefilled Vaccine syringe is drug or device?

Answer: Drug

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Registration Time and money

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Next Steps

Let leverage the digital and regulatory power (Digital Health Chapter)

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- ❑ Free membership
- ❑ Get News
- ❑ Get Education update
- ❑ Speaker role in Universities
- ❑ Advisory role in MedTech

More topics

- ❑ How to get product registration quicker
- ❑ Country regulatory system e.g. China
- ❑ Digital R&D
- ❑ Digital Manufacturing
- ❑ Digital Regulatory