Pharma 4.0

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What is Industry 4.0?

- **Industrial Revolution** (1800s)
- **Mass Production** (1900s)
- **Computerisation/Automation** (1980s)
- **Industry 4.0**

**Gross Domestic Product**

<table>
<thead>
<tr>
<th>Year</th>
<th>Stage</th>
<th>Technologies</th>
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<tr>
<td>1800s</td>
<td>Industrial Revolution</td>
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<td>1900s</td>
<td>Mass Production</td>
<td>Big Data and Analytics, Robotics</td>
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<td>1980s</td>
<td>Computerisation/Automation</td>
<td>Digital Twin, Artificial intelligence</td>
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<td>Additive Manufacturing, Integrated Systems</td>
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<td>Industry 4.0</td>
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Pharma 4.0 - The usual excuses.

But we work in Pharma with the following “excuses” -

• “We will just invent another block buster drug”

• “GMP’s won’t allow that!”, “QA blocks everything.”, “It’s just too hard.”

• “The “TGA” will not let you do it.”

Change Management
Chapter 1: Pharmaceutical Quality System
PE 009-14 (Part I) 1 July 2018

§1.2: ……. should facilitate innovation and continual improvement and strengthen the link between pharmaceutical development and manufacturing activities.

§1.4: (xi) Continual improvement is facilitated through the implementation of quality improvements appropriate to the current level of process and product knowledge;

But also in §1.6, § 1.10, § 2.9...... and a basic premise of a CAPA improvement.
Innovation

1800s-1900s: harvest and ship

1900s-1930s: create in factories

1930+: produce at home

until someone works out how to

until someone works out how to

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Has the hype been realized? Industry 4.0’s blind spot: People.

There are 345 million people working factory production jobs around the world. In contrast, there are ~1.5M robots, with ~250K being deployed each year. Considering that only 5.6 people are reportedly displaced by each robot, it’s clear that humans in manufacturing have a long run ahead of them.

People need to adopt the right mindset now, to be ready when it (Industry 4.0) really hits us.

Valuable datasets can be collected from humans enabling breakthrough productivity & quality improvements.

72% of factory tasks still done by people
68% defects are made by people
39% of engineers time collecting data
AUTONOMOUS VEHICLES

• Offer great advantages. No-stress commute, multitasking. **They come at a cost.**

• Big technology companies could convert transportation into a PAYG service and own so much data about people, patterns, routes and obstacles. A few who own the associated critical infrastructure. **Could exacerbate social inequality.**

• Entry level jobs related to transportation and the entire supply chain of the existing transportation system in production and service delivery (AI, robotics, low-cost computing), may permanently impact people’s livelihood, engagement and thereby their **sense of purpose to exist in society.**
Where does Australia stand?

The latest Harvard Growth Lab Atlas of Economic Complexity ranks Australia 93rd, lagging Kazakhstan, Uganda and Senegal, and only just ahead of Pakistan and Mali. (ABC News, Nov 1 2019)

That's despite Australia being the eighth richest country in the world according to the study, with a national per capita income of $US54,093 in 2017 (ABC News, Nov 1 2019)

Australia has the skills, the capacity and the ability to be an innovation pioneer for which government support is considered essential for future success and adoption of Industry 4.0.
Pharma 4.0 - Regulators are here to support industry and encourage innovation

$7bn product returns which could be used, if they were tracked via Blockchain.
Pharma 4.0 Examples: Microsoft – AstraZeneca

Digital Transformation Envisioning

- **Microsoft** facilitated it
- Part of the IT strategy
- Power BI used internally extensively within Microsoft (MS).
  - MS is a manufacturer of devices, surfaces etc
  - Coloured for “exception” reporting
  - Infer AI within their cloud big data -
- Microsoft advice - start small, but start.
- MS offers Azure Machine Learning as an IoT Edge Cloud
- MS offers PowerBI
Pharma 4.0 Examples:
3D printed body parts “bones”

Paul D’Urso – started 25 years ago!

https://www.youtube.com/watch?v=22XQYKD91qU&feature=youtu.be
Pharma 4.0 Examples: Tablet inspection – big data

Make tablets the same way our grand parents did! **Spitam**

- Critical e.g. human hair
- Control Strategies, filter, sieve, gowning
- Technology exists, use it

- But 500,000 tablets per hour
- 3D photos both sides
- 1,000,000 photos/hour 24TB/year

**Detects** - Spots, chips, misprints, capped, broken, stain, bumps, engraving
Pharma 4.0 Examples:
CAPEX doesn’t have to be exorbitant!

- Baxter Healthcare has employed 3D-Printing in secondary packaging applications.
  - One prototype developed was to hold glass vials that present safety and security issues when shipping.
  - Another prototype Baxter developed via 3D-Printing was for holding syringes in place so that a plunger device would not move. Parts were made quickly and within a month a tool was ordered for production.

Goes to show that relatively small CAPEX towards adopting Pharma 4.0 elements can go a long way in deriving Operational Excellence.
The power of Power BI
Pharma 4.0 Examples: RFID tags

• 2013 – **Richardson Police Department** enabled an asset tracking solution, $9,000 per car saved about ½ per day.

• Opportunities to sew RFID tags into clothes, autoclavable hand tools

• Readers in and out of wash areas.

• Low Power Wide Area Networks

• RFID can confirm temperatures too.
Pharma 4.0 Examples: Virtual Pharmacist

Guild Pharmacy of the Year 2019 - Harding's 24-hour Pharmacy, Annerley QLD

https://youtu.be/WTRJmBVvUMo
Lonza Cocoon™ Platform
ATMP’s and personalised medicines

The Cocoon™ system is based on an automated GMP-in-a-box concept for patient-scale cell therapy manufacturing. The goal is to provide a scalable, cost-efficient solution to address cell therapy manufacturing bottlenecks.

Mindset 4.0
Change is hard. Not Changing is fatal!

- Making the time/space
- Getting real results
- Picking the right fights
- Finding the talent
- Engaging others
- Building the teams
- Changing culture
- Establishing a process
- Surviving bureaucracy
- Working inside the squares

- Getting past ‘no’
- Fighting the resistance
- Maintaining momentum
- Sharing the benefits
- Motivation and incentives
- Financing innovation
- Convincing the market

Mindset 4.0 Training (Top Down)
What if we do it like this?

Give me problems, I’ll give you ideas.

Give me big ideas and I’ll give you solid plans.

Show me a plan and I’ll find all the risks.
Give me problems
I’ll give you ideas

Give me big ideas and I’ll give you solid plans

Show me a plan and I’ll find all the risks

Tell me the risks and let me get on with it
imagine develop evaluate act
PricewaterhouseCoopers’ implementation plan
Act now!

1. Map out your Pharma 4.0 strategy and champion.
2. Monitor “technology”.
3. Create and test small pilot projects.
4. Define capabilities needed.
5. Become expert in data analytics.
6. Transform to a digital enterprise.
7. Plan an ecosystem approach.

But before any of this, a Pharma 4.0 Mindset needs to be cultivated in our industry!
Thank you

Presentation is available on
https://www.pharmout.net/pharma-4-0/