Over the last 10+ years, many technologies have emerged with significant impact on pharmaceutical operations

<table>
<thead>
<tr>
<th>Technology</th>
<th>Description</th>
<th>Impact</th>
<th>In-use or tested by</th>
</tr>
</thead>
<tbody>
<tr>
<td>More efficient practices</td>
<td>Technology enabling higher productivity, better quality, …</td>
<td>Increase available capacity</td>
<td>Fette Compacting</td>
</tr>
<tr>
<td>Advanced analytics</td>
<td>Predictive maintenance</td>
<td>Increase quality</td>
<td>DSM</td>
</tr>
<tr>
<td>PAT technologies</td>
<td>In-line digital quality measurement</td>
<td>Higher quality</td>
<td>nere pharmaplan</td>
</tr>
<tr>
<td>Disposables</td>
<td>Single-use equipment for biologics</td>
<td>50% faster startup</td>
<td>Rentschler Biotechnologie</td>
</tr>
<tr>
<td>Standard technology platforms</td>
<td>Pre-defined technology platforms linked to R&amp;D</td>
<td>Faster scale-up and launch</td>
<td>AMGEN</td>
</tr>
<tr>
<td>3D printing</td>
<td>3D printing of solid dosage forms</td>
<td>Higher dosages available</td>
<td>APRECIAS Pharmaceuticals</td>
</tr>
<tr>
<td>Continuous manufacturing</td>
<td>Continuous blending, comp-ression, and film coating</td>
<td>10x faster production</td>
<td>Novartis</td>
</tr>
<tr>
<td>Advanced automation</td>
<td>Fully-automated packaging lines and warehouses</td>
<td>Reduced labor</td>
<td>Amazon</td>
</tr>
<tr>
<td>Modular plants</td>
<td>Container-sized suites or individual equipment that is assembled and shipped</td>
<td>50% faster start-up time</td>
<td>Merck</td>
</tr>
</tbody>
</table>

SOURCE: McKinsey analysis, expert interviews
However, Industry 4.0 is revolutionizing the pharma ops landscape along four dimensions:

- **Data, computational power, connectivity**
  - Sensors
  - Internet of Things
  - Cloud technology
  - Blockchain

- **Human machine interaction**
  - Virtual and augmented reality
  - Robotics and automation (collaborative robots, AGVs)
  - RPA, chatbots

- **Analytics and intelligence**
  - Automation of knowledge work
  - Advanced analytics and Artificial intelligence

- **Advanced production methods**
  - Additive manufacturing (i.e., 3D printing)
  - Renewable energy

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**End-to-end Digital thread – seamless data flow along the value chain / product life cycle**

SOURCE: McKinsey analysis
Contents

Industry 4.0

WHY now?
– Digital trends

WHAT can be done? -
Examples of what is already happening today

HOW to make it happen? -
Approach
Is it time to now switch gears for Industry 4.0 in Pharma industry?
Digitization changes our world and generates a data explosion...

By 2020, there will be **21 billion** connected devices in a global Internet of Things, producing an ever-increasing amount of data.

90% of the world’s data today has been created in the last 2 years only.

Each day we create **2,500,000,000,000,000,000** (2.5 quintillion) bytes of data. This would fill 10 million Blu-ray discs, the height of which, stacked, would equal the height of 4 Eiffel towers.
… triggering new business models that are disrupting traditional ones

**World’s largest Taxi company**
- Owns NO
- Taxis

**World’s largest Accommodation provider**
- Owns NO
- Real estate

**World’s largest Phone companies**
- Owns NO
- Telco infra

**World’s most Valuable retailer**
- Owns NO
- Inventory

**Most popular Media owner**
- Owns NO
- Content

**SocietyOne World’s fastest Growing bank**
- Owns NO
- Actual money

**NETFLIX World’s largest Movie house**
- Owns NO
- Cinemas

**World’s largest Software vendors**
- Owns NO
- Apps

SOURCE: Internet; public information
This disruption is also now happening in healthcare with technology companies heavily investing and leading Pharma companies also embracing digital technology.

### Atypical disrupters in pharma & healthcare

<table>
<thead>
<tr>
<th>Company</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amazon</td>
<td>Invested $1 billion to buy mail order pharmacy company PillPack</td>
</tr>
<tr>
<td>Google</td>
<td>Invested in Oscar Health, joining GV, Verily Life Sciences, and CapitalG</td>
</tr>
<tr>
<td>GE</td>
<td>Invested in Evidation Health (generates real world evidence) &amp; Verana Health (focused on ophthalmology data)</td>
</tr>
<tr>
<td>Apple</td>
<td>Acquired Beddit (sleep monitor company) &amp; Glimpse (personal health data platform)</td>
</tr>
<tr>
<td>Intel</td>
<td>Invested in Lumiata (uses predictive analytics to improve care in hospitals) &amp; EchoPixel (develops tools to enable non-invasive colon cancer screening)</td>
</tr>
</tbody>
</table>

### Other tech investors in recent past

- **Microsoft**
- **Oracle**
- **Cisco**
- **Amgen**

### Bold pharma investments in digital

- **2012:** Moved supply chain to cloud
- **2015:** Complete visibility into the status of products at all times; identify demand and quickly alert the best production facility to manufacture
  - Pfizer is also looking to move into the e-commerce space for prescription medications in the near future
- **Merck:** Uses Hadoop to crunch huge amounts of data so it can develop vaccines faster
  - 15 billion calculations and more than 5.5 million batch-to-batch comparisons to link characteristics in fermentation phase to yield in final purification
- **Amgen:** Use of machine learning & deep learning to better diagnose osteoporotic fractures

**Source:** [cbinsights.com/research/top-tech-companies-healthcare-investments-acquisitions/](https://cbinsights.com/research/top-tech-companies-healthcare-investments-acquisitions/); Amgen website; [www.informationweek.com](https://www.informationweek.com); [rctom.hbs.org](https://rctom.hbs.org/)
As we think about Industry 4.0 in Pharma, it is the “new lean” of a decade ago

<table>
<thead>
<tr>
<th>Lean method examples</th>
<th>Industry 4.0 method examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Visual management</td>
<td>▪ Digital Performance management</td>
</tr>
<tr>
<td>▪ Pareto (e.g., OEE)</td>
<td>▪ Data lake (1 million times more data)</td>
</tr>
<tr>
<td>▪ MIFA</td>
<td>▪ Machine learning</td>
</tr>
<tr>
<td>▪ Ishikawa</td>
<td>▪ Digital twin</td>
</tr>
<tr>
<td>▪ Gemba/Process Confirmation</td>
<td>▪ “Waze”</td>
</tr>
<tr>
<td>▪ Zero waste mindset</td>
<td>▪ App store</td>
</tr>
<tr>
<td>▪ Google glasses</td>
<td>▪ Digital mindset</td>
</tr>
<tr>
<td>▪ Enhanced reality</td>
<td>▪ Video analysis</td>
</tr>
<tr>
<td>▪ Video analysis</td>
<td>▪ Machine learning</td>
</tr>
</tbody>
</table>

McKinsey & Company
Five major paradigm shifts are driving the way data is used in pharmaceutical operations

**A Data**
- Data lake
- Analytics platform

**B People**
- New roles and capabilities
- Digital performance culture

**C Regulations**
- Proactive regulatory strategy

---

**True product masters**
Quality-by-design by using insights from CMC, manufacturing, Quality and customers. Parametric release.

**Real-time Digital Twin**
Complex analytics models accurately mirror assets, people, and supply chains. Simulations, optimizations, e-validations, master date update

**Predictive Analytics**
Live prediction of deviations, quality outcomes and demand. Proactive interventions to ensure reliability and agility.

**Digital operations assistance**
Augmented reality elevating operators reliability (human error reduction/digital SOPs) and efficiency (real-time task allocation)

**Knowledge work automation**
Digital robots execute (e.g., supply planning/scheduling, change mgmt) or support decision making (e.g., CAPA, portfolio) based on self-learning algorithms

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**Vertical and horizontal digital integration – From supplier to patient**
The question is NOT: is this relevant for us as well …

… BUT RATHER: How can we shape the future using it?
WHAT

can be done?
Examples of what is already happening today
In 2018, we set out to identify the factories at the forefront of the Fourth Industrial Revolution – the “lighthouses”

- First-of-its-kind global network of lighthouse production sites has been created, containing of 16 leading factories which overcame the prevalent “pilot purgatory” and achieved significant financial and operational benefits from at-scale Fourth Industrial Revolution (4IR) technology deployments
The sixteen recognized lighthouses cover a broad range of geographies and industries.
The reported KPI improvements show that the lighthouse factories achieve significant impact from the at-scale technology deployments.

<table>
<thead>
<tr>
<th>KPIs improvements</th>
<th>Impact range observed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Productivity</strong></td>
<td></td>
</tr>
<tr>
<td>Factory output increase</td>
<td>10-200%</td>
</tr>
<tr>
<td>Productivity increase</td>
<td>5-160%</td>
</tr>
<tr>
<td>OEE increase</td>
<td>3-50%</td>
</tr>
<tr>
<td>Quality cost reduction</td>
<td>5-90%</td>
</tr>
<tr>
<td>Product cost reduction</td>
<td>5-40%</td>
</tr>
<tr>
<td>Energy efficiency</td>
<td>2-50%</td>
</tr>
<tr>
<td><strong>Agility</strong></td>
<td></td>
</tr>
<tr>
<td>Inventory reduction</td>
<td>10-90%</td>
</tr>
<tr>
<td>Lead time reduction</td>
<td>10-90%</td>
</tr>
<tr>
<td>Time to market reduction</td>
<td>30-90%</td>
</tr>
<tr>
<td>Change-over shortening</td>
<td>30-70%</td>
</tr>
<tr>
<td><strong>Customization</strong></td>
<td></td>
</tr>
<tr>
<td>Lot size reduction</td>
<td>50-90%</td>
</tr>
</tbody>
</table>
Bayer's Garbagnate (Italy) site was the only pharmaceutical site to be nominated by the World Economic Forum.
Case example#1: Transformation of the site into a digital plant to support growth

**Starting point/ business need**

- **Volume increase of 30% requiring a 24/7 production cycle**

- **Increased portfolio complexity** – leading to an increase in c/o by 26%

- **50% additional workforce** with limited previous experience

**Extracting data from different sources**

- SAP
- LIMS
- ERP
- Data warehouse
- PLC
- Excel

**Creating a standardized “Plant Data Lake”**

- Quality
- Production
- Maintenance
- Supply chain
- Equipment
- Personnel
- Costs
- ...

**Driving impact through selected Digital & Advanced Analytics applications**

1. Digital performance management and deterioration warning
2. Augmented reality and assistant to reduce change over duration
3. Reduce breakdowns by using Advanced analytics to detect causes
4. Optimize QC scheduling using advanced analytics
5. Trouble-shooting app suggesting experienced experts and optimum machine settings
6. Plant-wide digital performance management
7. Reduce deviations by using Advanced analytics and Natural Language Processing
8. Product mastery by advanced modelling on production parameters

**Change management & capability building**

Scalability management (global roll-out, eco-system of vendors, validation, etc.)
The resulting impact across areas exceeded expectations

- **QC lab productivity**: +50% increase of lab productivity by applying advanced schedule optimization

- **Changeover**: -30% reduction in time on tablet press using smart glasses

- **OEE**: +40-50% OEE increase on packaging line supported by AA insights and Digital performance management

- **Deviations**: -80% reduction in deviations since applying advanced analytics (0% recurring)

- **Deviation handling/closure time**: -90% reduction of deviation closure time by AA based deviation advisor tool
VIDEO
Indian pharmacos have also successfully implemented several use cases. Some examples:

1. **Yield improvement in API:** Advanced analytics helped identify critical parameters that impact yield. *Yield improvement of 5-7%*

2. **Invalidated OOS reduction:** Identified ~10% of tests likely to contribute to ~60% of future invalid OOS. *35% reduction in OOS within 1 month of implementation*

3. **Cost reduction in indirect spend:** Use of NLP and fuzzy logic to categorize spend into actionable categories & identify ideas to *reduce spend by 3-5%*

4. **People analytics to reduce attrition:** Identified granular reasons and recommendations to *address 65+% of QC analyst attrition*
To make it happen? – Approach towards industry 4.0
732 respondents

- 14% N America
- 28% Europe
- 13% LatAm
- 45% Asia
Industry 4.0 is a top priority for manufacturers
Variation exists across countries

Top priority 68%
However, ASEAN companies are still struggling to make Industry 4.0 a reality.

**Aware of I4.0**

Respondents on the implementation of Industry 4.0, Percent

- 43% I4.0 strategy defined
- 52% Clear I4.0 roadmap defined
- 47% Owners for use cases defined
- 13% Implementation launched

**Digital company**

**Reasons holding back implementation**

- Problems defining clear business plan
- Siloed data not integrated across BUs
- Limited talent to execute roadmap
- Concerns of Cybersecurity risks
- Limited coordination across BUs

*SOURCE: McKinsey Industry 4.0 ASEAN Survey 2017*
Additionally, companies face change management challenges

A digital transformation is challenging because …

- …involves **many stakeholders from different units**, with potentially diverging agendas (e.g., Business units, Risk Management, IT, Operations, …)

- …requires a **radical change of mindset** in many aspects

- …creates completely **new jobs** and **competences** (e.g., data scientists, data owners, data translator, …) and the evolution of traditional jobs (e.g., CRM)

- …requires the **capability to react fast and frequently revise plans** to adapt to a very changeable and unpredictable market environment (e.g., new data technologies)

It is essential to outline cornerstones of a **robust change management program** to ensure effective execution.
Companies typically look to capitalize on I4.0 opportunity in one of three horizons of impact / scope

**Experiencing Horizon**
- Launch use cases that are high impact but limited in scope – typically aimed at one specific unit or process
- The objective is to build up experience and generate momentum

**Exploring Horizon**
- Launch "Lighthouse" projects – typically aimed at a site
- The objective is to demonstrate full potential of a given technology and serve as inspiration for the company as a whole

**Envisioning Horizon**
- Roll out digital across value chain
- Fully utilize machine learning models that can actively suggest optimization measures

SOURCE: McKinsey white paper "How data is changing pharma operations world"
There are four common themes that we have seen translate to success regardless of the scope / impact horizon pursued:

1. Set the aspiration – Define the future organization
2. Identify opportunities for improved operation; Identify use cases that will drive impact
3. Prioritize and sequence use cases; Define approach to scale across network
4. Invest in strong Internet of Things (IoT) infrastructure for data capture
5. Create an advanced analytics platform and build in house capabilities
6. Fit or retrofit physical technology to robotic or automated processes
7. Avoid getting stuck in pilot purgatory
8. Invest in right number & type of resources
9. Focus disproportionately on culture & mindset shift

“Test & implement” and invest the appropriate resources

Build a “digital factory” to initiate; deliver a digital transformation and drive culture change

- A digital “factory” is a construct of 10-50 teams, each with 8-12 cross-functional participants
- Each team works in agile sprints
- All teams are given some license to experiment
- Senior leaders in the organization sponsor 1-2 elements each of the digital factory

SOURCE: McKinsey
Finally, successful companies focus on talent needs and organizational shifts to enable success.

- **Develop and fine-tune algorithms to find patterns and get business insights**
- **Drive the design and execution of the overall Analytic and Digital strategy**
- **Support the design, development and maintenance of the data architecture**
- **Conducts targeted analyses, and interprets implications**
- **“Translate” business needs into advanced analytics-amenable questions; interprets insights and derives recommendations**
- **Develops robust and scalable solutions to support core business processes**
- **Responsible for the core business function; identifies sources of value and defines objectives**

**Chief Analytics / Digital Officer**
- Develops targeted analyses, and interprets implications
- Conducts targeted analyses, and interprets implications
- “Translate” business needs into advanced analytics-amenable questions; interprets insights and derives recommendations
- Develops robust and scalable solutions to support core business processes
- Responsible for the core business function; identifies sources of value and defines objectives

**Analysts**
- Business owners
- IT data specialists
- Solution Architects
- Chief Analytics / Digital Officer
- Data Scientists
- Translator
THANK YOU

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