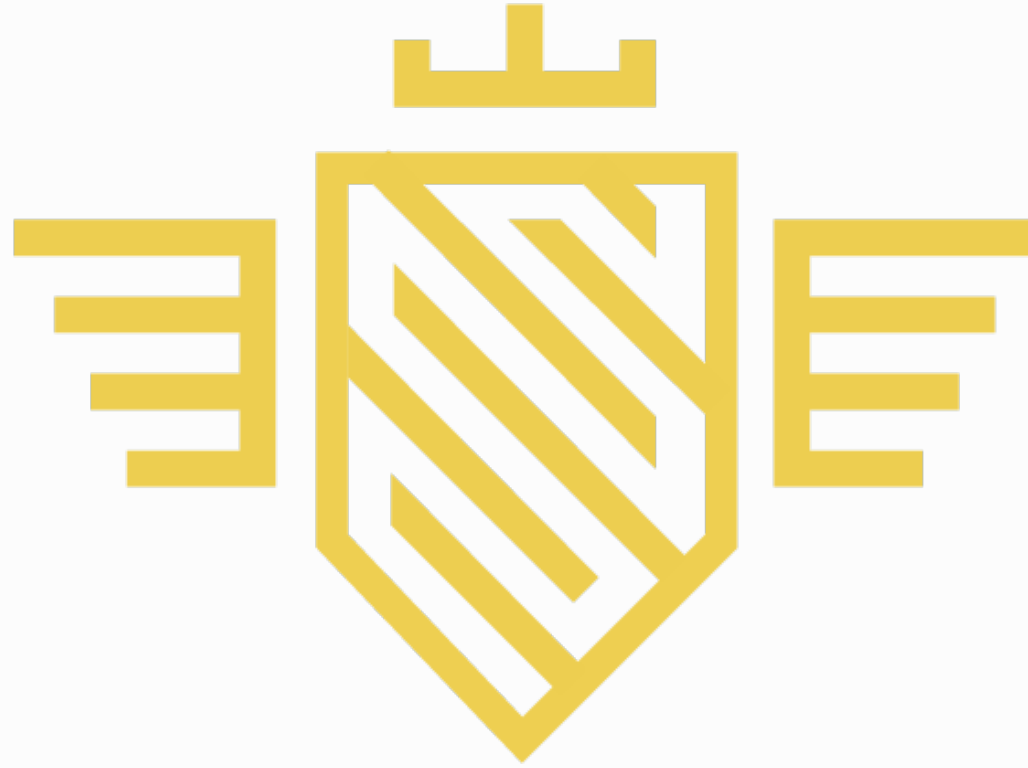


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THE UNITED ALLIANCE

PASSION FOR LIFE | PURPOSE TO SERVE | POTENTIAL TO CREATE



Medical Products: Manufacturing the Future

1. Why are we here?

2. What is the solution?

Innovative Technologies

Innovative Strategies

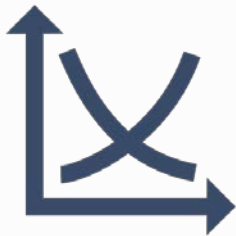
Innovative Policies

PROBLEM | Today's manufacturing causes cost, shortages & recalls



Shortages

Not producing enough & not resilient to shocks



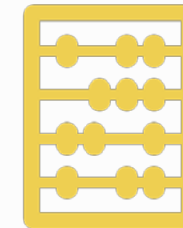
Defects

Flaws that effects patients (e.g. recalls) or production quality



High costs

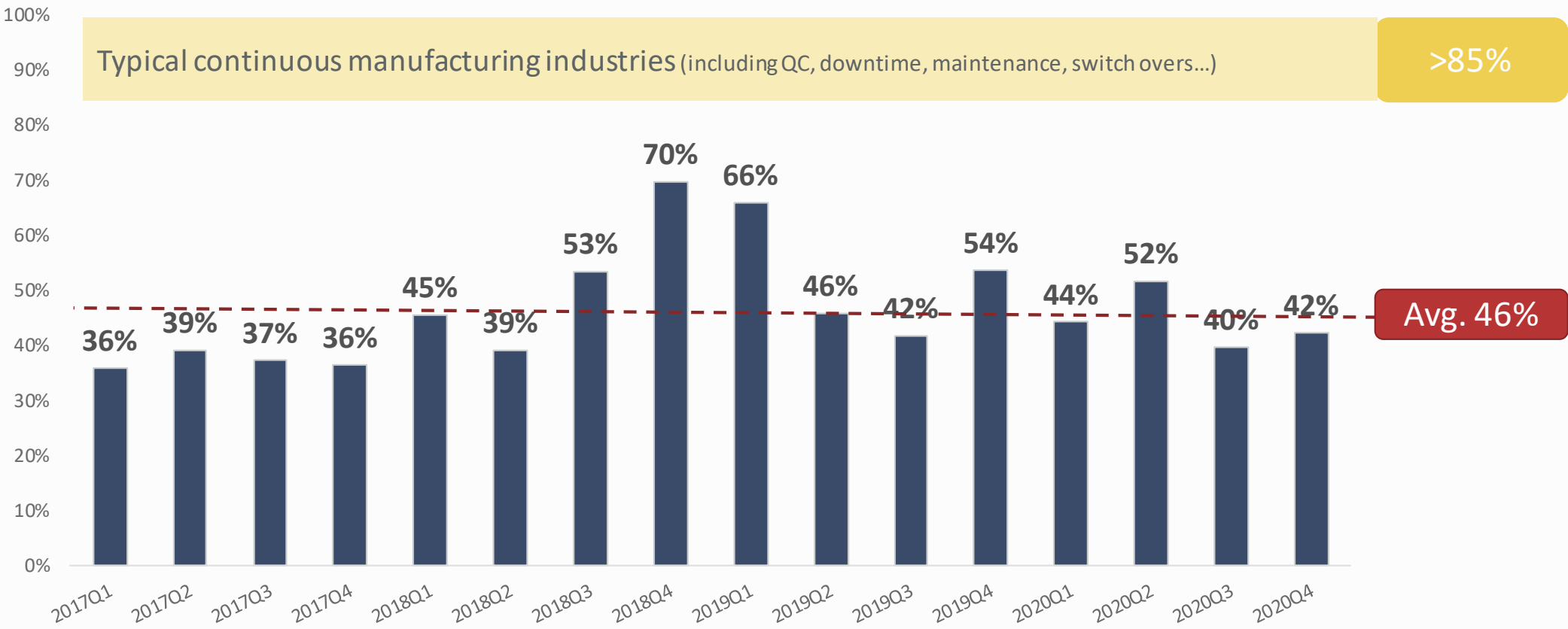
Not competitive inter-national (or inter-industry)





Shortages | On average, our factories are closed ~4 days a week

US Pharmaceutical Plant Operating Hours as % of Available Hours



1

Innovative Technologies Today

1. **Run more shifts** (quick, safe, cheap)
2. **Modular Plant with Design** for Rapid change over and stop-start
3. **Modern automation** and control systems with in-line QC and real-time feedback
4. **Continuous, LEAN “batching”** i.e. replace most “stop & checks” within each batch



Innovative Technologies Tomorrow

1. **AI evolved** – generalized beyond good labeling and algorithm weightings
2. **Bio synthetics** to become a core manufacturing approach to drug design
3. **Combined “Device and drug”** solutions become the norm
4. **Individualized drug manufacturing** for both patient efficacy and production efficiency



Innovative Strategies for Manufacturers

1. R&D, Production and Commercialization to **co-design patent and FDA approval** submissions to scale for mass production
2. **Designing out human mistakes** to reduce defects
3. **Condition-based monitoring** maintenance and operating philosophy



Innovative Policies

1. **FDA Approval Process** makes it difficult to upgrade manufacturing processes
2. **Redesign GMP standards** and audit procedures to **reward technologies** that provide faster, more accurate and more specific measurements. **No longer *need* to be one-size fits all!**
3. **Democratize drug development**
4. Incentives for increased production



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THANK YOU