speed to approval

Your late stage customization destination. Our world.

launch

# Late Stage Customization

At PCI, ensuring life-changing medicines reach those who need it most is our highest priority. As a truly integrated global CDMO, we are manufacturing, packaging and supply chain experts, harnessing our experience and expertise to deliver you a seamless solution with the ultimate aim of improving the lives of patients.

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As therapies become more complex with lower patient numbers per SKU and are often of a higher value, the complexity of stock management increases; however, by applying the principles of Late Stage Customization (LSC) and through investment in dedicated technoloy, we are able to offer a streamlined process that delivers cost and time efficiencies while minimizing risk.

Digital printing enables customization of brite stock late in the production process or just prior to shipment, reducing supply chain risk through a more efficient stock management process. This service includes the in-line printing on blank roll stock, eliminating the need to pre-print multiple artworks and allowing for small unique batch production.

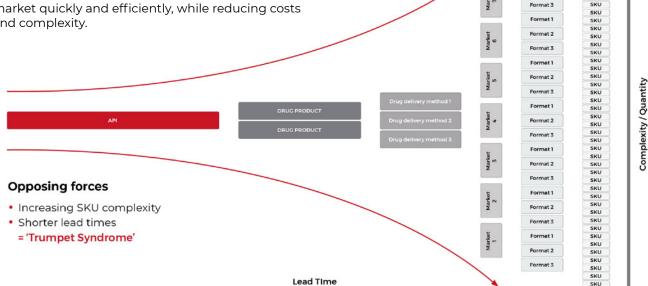
SKU SKU SKU SKU SKU

Format 1

Format 2

### Late Stage Customization

Late Stage Customization (LSC) also referred to as digital printing, delivers an accelerated route to market quickly and efficiently, while reducing costs and complexity.





# **Overview**

## Why Digital Printing?

- Printing digitally replaces the traditional plates and printing press
- Capability to print on labels, pouches, blisters, and cartons
- Ability to print both fixed and variable text including:
- SKU specific artwork
- Serialization
- Country specific language and/or protocols

#### **Process Advantages**

- Speed to study & market!
- Quickly react to forecast changes, seasonality, and promotions
- No component lead times with base stock in-house
- Reduce lead time for packaged stock
- Maximize use of product with short expiration dates or limited stability data
- Reduce complexity in managing inventory
- Reduce change overs and line clearance

#### **Industry Challenges**

#### **Clinical stage**

- Scarce and expensive drug product
- Booklet labels: costly, complex, and patient unfriendly
- Large percentage of booklets never opened
  - Risk of patients being non-compliant
- Often countries are late in the clinical protocol and booklet labels need to be reordered or new labels applied
- Shelf-life updates often result in relabeling activities
- Increase in adaptive trials

#### **Commercial stage**

- Small batch sizes
- MOQs drives waste and cost
- Agility to react quickly to market needs/ changes
- Country specific labeling increases complexity
- Availability and cost of bulk
- Sustainability
- Warehouse stock value

# **Financial Benefits of LSC**

- Reduce waste of expensive drug products
- More efficient use and distribution of expensive drug products
- Decrease need of a second manufacturing run of drug products
- No minimum order sizes from component vendors
- Reduced loss from overstocking
- Reduced stock holding in market with smaller MOQs
- Positive effect on cash flow
- Business continuity planning without the need for excessive safety stock

