21st century manufacturing of injectable pharmaceuticals

This infographic explores the factors changing the development and production of sterile injectables.

The need for greater manufacturing agility

With growing competition and smaller patient populations, companies are driving to be first to clinic or market. Flexibility is a must for different therapy types and containers.

Overall trends:

- ↑ Number of therapies
- ↑ Product launches
- ↑ Container variety
- Regulatory demands for modernizing manufacturing
- Shorter product lifecycles and increased competition

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therapies in late-stage clinical development (1), **yet only…**

46

novel therapies on average approved by CDER annually from 2014 through 2023 (2)

65%

of drug shortages caused by manufacturing and quality issues (3)

$356B

of worldwide branded sales at risk from patent expiration in 2023 to 2028 (4)

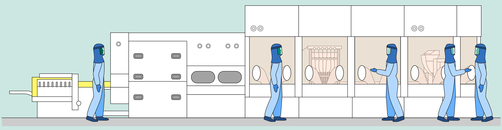
Issues with conventional fill-finish

Today's therapies are more complex, but many people are using the same approaches and equipment from 20 years ago – with the same aseptic issues.

Built for blockbusters:
High throughput, slow changeover, single container format

Custom designs:
Inflexible, long build timelines, high costs, hard to replicate

Aseptic issues:
Glove ports, operator interventions, particle generation



What's next for filling equipment? It must provide exceptional sterility assurance, comply with global regulatory requirements, and drive process repeatability and reproducibility via automation.

How to modernize fill-finish

The aseptic filling workcell approach

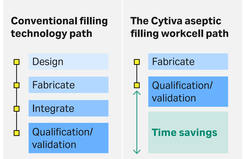
The workcell approach is well-suited for

1. Oncology cytotoxics, antibody drug conjugates (ADCs), monoclonal antibodies
2. Novel biologics and biosimilars
3. Any high-mix, multi-product facility: (e.g., contract manufacturing organizations for clinical and small-scale commercial fill-finish or generics)
4. Drugs of the future, including gene therapies and personalized medicines

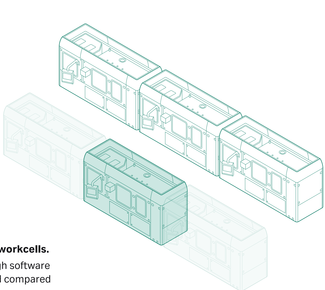
An integrated combination of gloveless isolator and filling robotics, which provides a high level of aseptic assurance and quality for high-value therapies.

Key benefits

1. **Supports speed to market:** Build and scale out quickly. Provides ready, flexible manufacturing capacity for fill-finish.
2. **Meets needs of low-volume, high-value pipelines:** Delivers flexibility for vials, syringes, and cartridges with fast changeover.
3. **Fixes aseptic processing issues** with gloveless robotic approach.
4. **Uses a standard design** for fast build, deployment, and validation. Reduces infrastructure, floor space, and personnel requirements compared with conventional isolators.



Key differences vs conventional systems



Scale out, not up, with additional workcells.
Add capability for new recipes through software changes. Much smaller space needed compared with conventional isolators.

Focus on value-added work: Uses only nested, ready-to-use containers.

Image courtesy of Stevanato Group.

Press-fit vial closures: Simplify capping and eliminate particles vs aluminum crimp caps.

Image courtesy of ARaymondlife.

CDER is Center for Drug Evaluation and Research, US Food and Drug Administration.

References

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