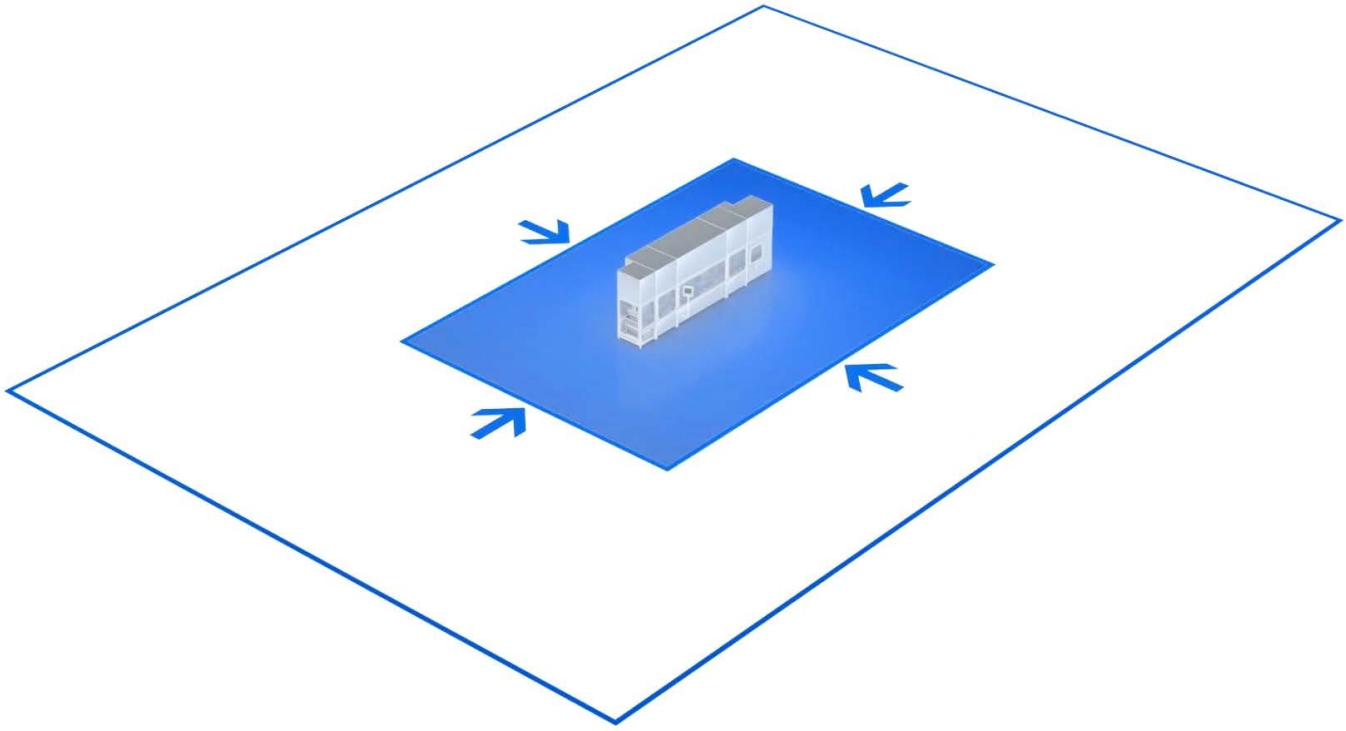
Changing the pharma game

Almost everything in drug manufacturing is about quality and time. Medications need to be produced in ever-smaller batches and shorter cycles while adhering to stricter regulations. In short: The paradigm changes. By embracing tried-and-true standardization concepts, drug manufacturers can elevate their operations to a whole new level.

Challenge

Existing pharma manufacturing models had been designed for filling as many units as possible of one blockbuster product on a dedicated line. Yet if you're a pharma company dealing with new therapies, you're likely bringing to market a higher number of more complex injectable drugs: biologics, cell and gene therapies. As these are more targeted, much fewer quantities are needed – sometimes only a few 100,000 units. As a result, your weekly production schedule needs to be much more flexible.

But there is good news: The latest generation of filling machines can fill either syringes, vials or cartridges in a flexible manner – and thus save precious clean room space.



The containers are fixed in a plastic grid (the nest), which is in turn boxed in a tub and sterile-packaged into a plastic bag. Due to the pre-sterilization, the tubs can go into filling operations right away. Hence, one also speaks of aseptic ready-to-use (RTU) packaging.

The challenge:
Taking RTU to the next level

So far, so good. Yet machine parts still have to be changed when switching from one container format to another, and currently available RTU packaging solutions require drug manufacturers to fit the filling machines to the specific tub format. So pharma manufacturers have to optimize the machine for each of these products individually. That also means they are doing the exact same work multiple times.

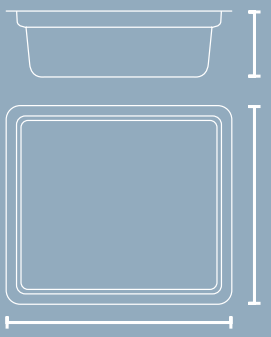
Wouldn't it make sense to standardize this part of the process and take RTU one step further?

Innovation

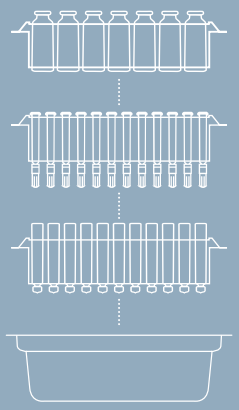
Flexibility through standardization

Creating a standardized nest and tub format for pharmaceutical manufacturing is much like the standardized containers used to ship freight. By having a uniform size and shape, there's no need to use different ships for different containers, no need for specialized cranes or different vehicles or rail cars for transporting the containers to their final destination. Having a standard makes the whole process more efficient. The same is true on drug filling lines.

ALL IN ONE TUB

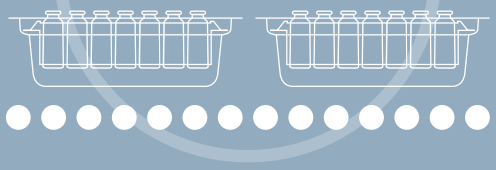


Vials, syringes and cartridges in versatile sizes all come in the same tub. The tubs are standardized according ISO 11040-7.



One single tub fitting for any nest results in less changing of machine parts when switching between containers.

That means various drugs can be filled in different containers on one line with little changeover time in between.



iQ™: Teaming up for innovation

Only close cooperation brings innovation. Hence, SCHOTT is developing the iQ™ platform in collaboration with the world's leading filling line and elastomer component suppliers to ensure the offering of flexible container systems.

COMPATIBLE WITH +30 MACHINE PLATFORMS

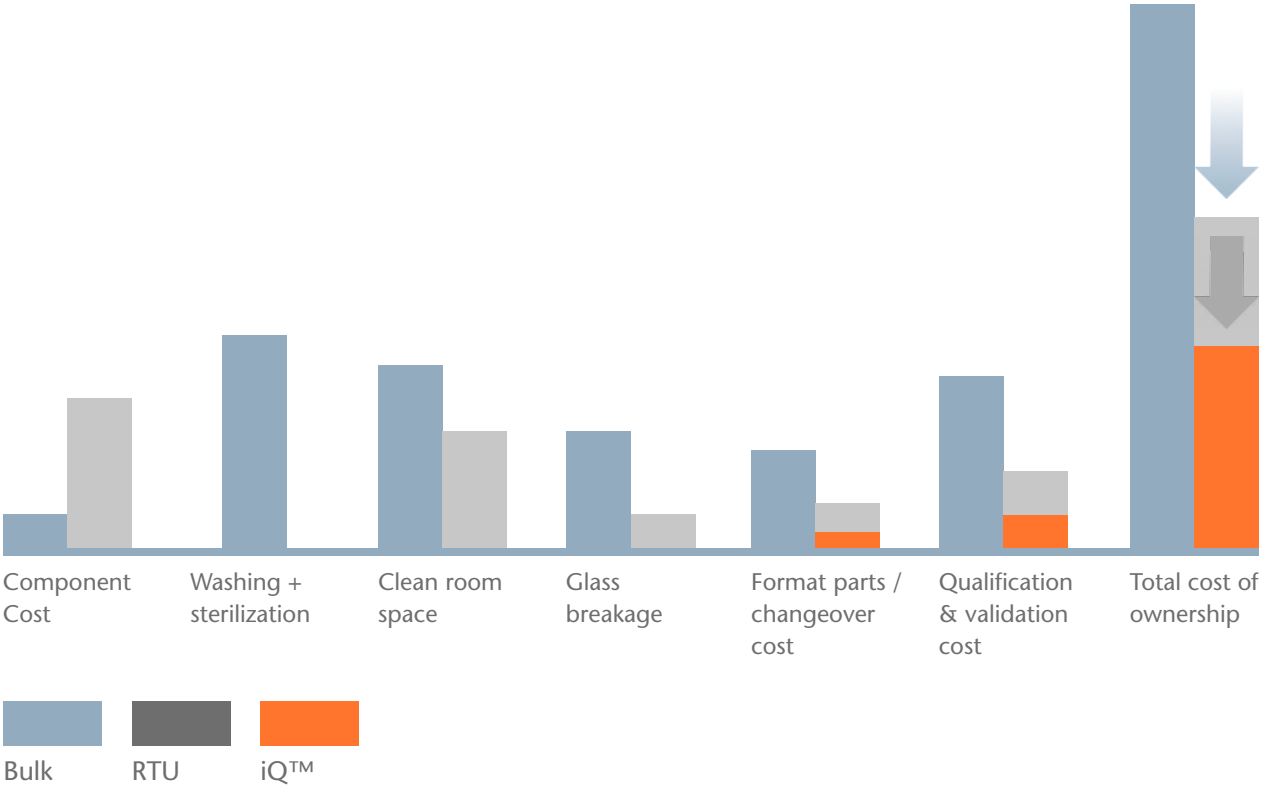
iQ™ matches a broad range of filling lines from all the leading and also upcoming vendors

INCLUDES PRE-VALIDATED CLOSURE COMPONENTS

iQ™ includes a set of pre-validated elastomer components, helping pharma companies to lower test efforts

Taking the TCO perspective

SCHOTT has performed concrete case studies on behalf of pharmaceutical companies, and they show: If manufacturers move from bulk to RTU, they can already achieve a lot of savings. But with the iQ™ platform, they can gain even more benefits. A toolset developed by SCHOTT helps manufacturers to find out about their own TCO profile and identify potential savings with iQ™.



People

Standardize to simplify

Gregor Deutschle, Director Business Development Sterile Solutions, on the advantages of standardization.

Next

Ready for future manufacturing

As manufacturing units become ever smaller and more flexible, new possibilities come into reach. For example, manufacturing units could be placed on a ship and support off-shore manufacturing.

What’s your next milestone?

Contact

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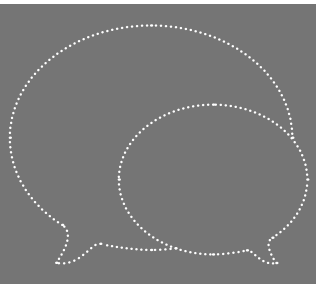

Links

More about iQ™