

# Emerging leaders in generics manufacturing



## Opportunities for growth and expansion

The generics industry is poised for some major shifts over the next few years thanks to more products, new markets and higher-margin activities. Let's look at learnings from the current landscape to understand where the industry is headed.

**3,200+** companies involved in API production

**130** Less Established companies with few products or limited experience supplying APIs to regulated markets

**215** Established companies with a long track record of supplying APIs to regulated markets

**582** Potential Future companies have interest in supplying regulated markets, but with limited or no known performance

## Regional strategies

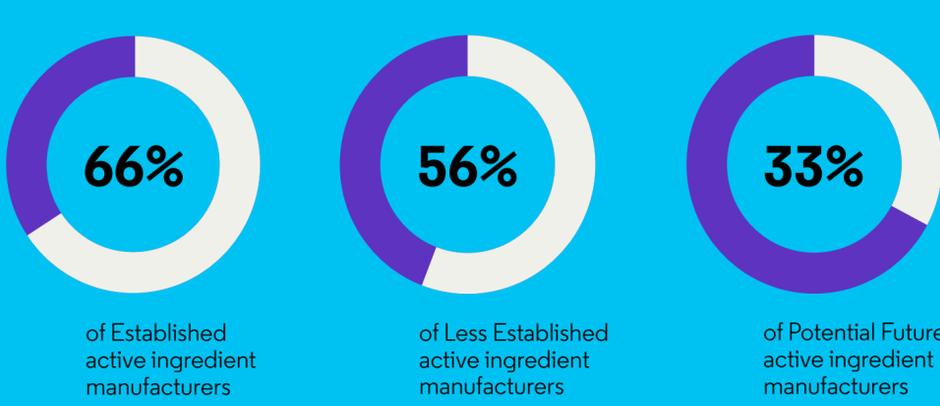
### Average number of APIs in a manufacturer's portfolio

India and Mainland China are focused on establishing deep and broad portfolios with products they can distribute internationally and/or globally. North America and the EU 5 are more likely to specialize in manufacturing niche products.



## Companies are diversifying their capabilities

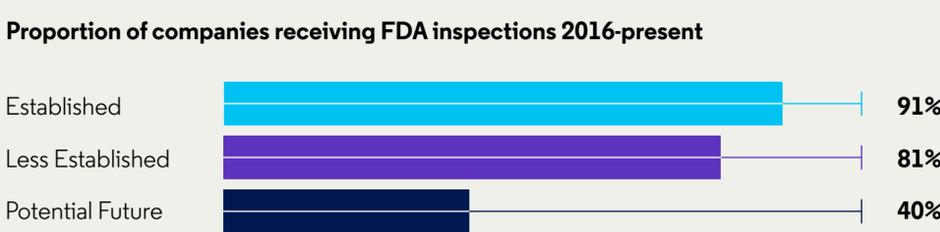
Many manufacturers are affiliating themselves with finished dose or U.S. generics activity.



## Maintaining quality standards is more critical than ever

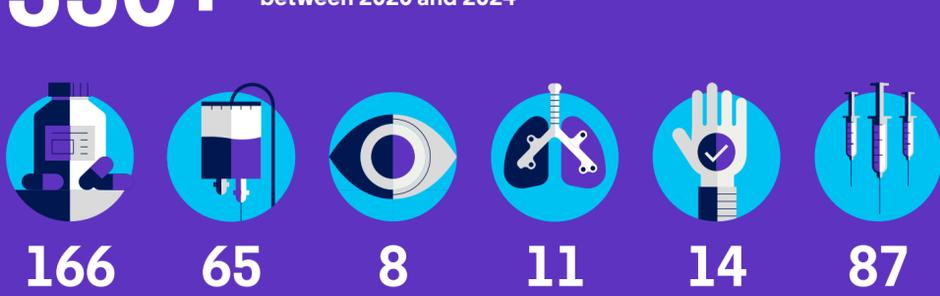
58 Potential Future suppliers have been inspected since 2016 but do not hold active DMFs ... yet.

### Proportion of companies receiving FDA inspections 2016-present



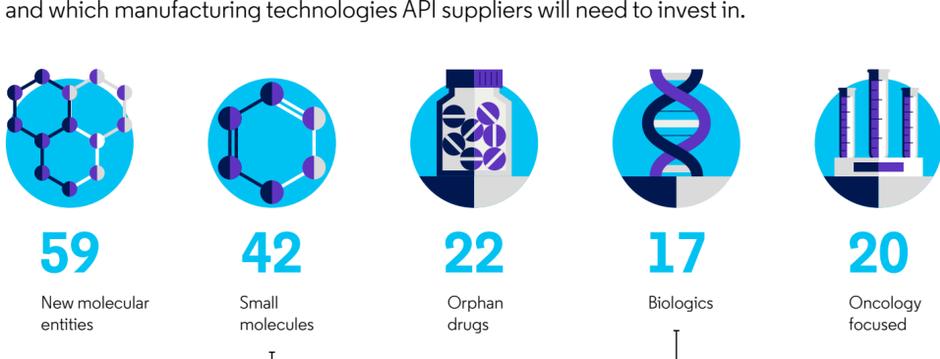
## New generic launches will involve advanced manufacturing technologies

**350+** products will lose exclusivity between 2020 and 2024



## Investment opportunities in specialty products

2018 U.S. FDA novel drug approvals serve as an indicator for where the market is going and which manufacturing technologies API suppliers will need to invest in.



## Characteristics of an emerging leader

Regardless of a manufacturer's current capabilities, firms can take advantage of the many opportunities in the generics space.



## Grow your generics or API business

Strategically develop your portfolio, gain insight on when drugs go off patent, and penetrate new markets. Visit our website to learn more: [clarivate.com/genericsintelligence](http://clarivate.com/genericsintelligence)

All data used in this analysis was derived from Newport, a Cortellis solution