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10 Reasons Formulation Complexity Is On The Rise In Steriles

patheon

Complexity is rising in sterile injectables, driven by factors that include, but are not limited to, formulation and delivery.

Reduce complexity and save time on the way to IND authorization and first-in-human trials.

1

Despite orphan drugs being notorious for their high costs and risk factors, the market is projected to grow at 13% CAGR from 2020-2024[12]. One driver of this growth is the financial incentives and benefits companies are receiving for new biologics that pertain to orphan drugs.

2

Prior to the COVID-19 Pandemic, the global mRNA therapeutics market was estimated to reach ~3B by 2026[2]. Complex formulations that deliver mRNA or DNA using lipid nanoparticles are on the rise. These formulations behave like oil and water emulsions, which increases complexity in formulation as well as compounding.

3

Highly potent molecules are on the rise. Oncology therapies seem to be aiding in the increase, since most of these therapies are highly potent molecules.

4

Large-molecule drug delivery through subcutaneous injection, which can complicate formulation, is a growing trend. Most of these drugs are highly concentrated, which can make handling more difficult.

5

More companies are scanning for companion biomarkers to help predict likely drug product pharmacodynamic responses, even in healthy Phase I patients, and therefore may want to test multiple formulations of drug product strength after Phase I.

6

Trials in multiple countries come with increasingly complex regulatory requirements.

7

More complex formulations in turn create additional work for regulatory bodies, which now have to review both the formulation process and how to validate it. Reviewers will look for a strong scientific rationale that supports the validation approach.

8

The growing appeal of drug repurposing – choosing existing molecules and searching for new indications– can add requirements to update formulation and provisioning while also ensuring cost savings. Costs of bringing a repurposed drug to market have been estimated to be US$300 million on average, compared with an estimated ~$2–3 billion for a new chemical entity.[3]

9

Every week brings more FDA fast-tracking of molecules from Phase II to Phase III and pivotal trials, often in less than a year. For certain niche indications, a client's Phase II drug can pass requirements for registration batch and even first commercial batch.

10

New pharma companies may not be aware of the product volumes needed to support the clinic, stability studies and testing. For example, a trial with 20 patients and three doses per patient may need an additional 1,000 vials for stability and 300 vials for testing purposes. Moreover, typical line loss of drug product can approach hundreds of milliliters.

1 EvaluatePharma® Orphan Drug Report 2019, © Evaluate Ltd.
2 EvaluatePharma: Mckinsey analysis February 2021
3 Nosengo, N. Can you teach old drugs new tricks? Nature 534, 314–316 (2016)

Given all this complexity, Thermo Fisher Scientific is a natural choice for a small pharma or biotech company because we can provide formulation solutions that add flexibility and speed into your workflow. Our formulation experts have helped clients receive more NDA approvals than any other CDMO—with 109 products between 2010 and 2019.

Contact us now to learn how we can help address your complex formulation challenges.

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