



"One of the leading sources of drug candidate failures will be due to unsuitable GMP ingredients that are part of the final dosage formulations. With the high cost of development and delivery, the Pharmaceutical industry should rely more on their Excipient and API manufacturers to ensure the products being supplied

are suitable for their intended end use to accomplish their desired development outcomes."

- Tom Donnelly, Director of Sales & Marketing, BioSpectra



"Based on market trends, I believe there will need to be an increased focus on improving therapeutic outcomes and enhancing the overall patient experience, particularly in the area of injectable biologics that require self-administration. In addition to effective drug formulations, it will be critical to ensure that patients' needs are effectively understood and that we create delivery systems patients not only can use, but want to use, and are actively encouraged and motivated to continue to use. Successful delivery of biologics will depend on integrated systems that link the container and device, and incorporate an integrated approach to design for affinity, effective training and onboarding, and creative solutions (including gamification and connected health technologies) to improve adherence."

- Graham Reynolds, Vice President, Marketing & Communications, Pharmaceutical Delivery Systems, West



"Fixed dose combinations (FDCs) will have a significant impact in multiple dosage forms throughout the next several years. The US Food and Drug Administration recently issued new guidance giving some additional exclusivity for filings with at least one new drug in the FDC product. A 'new' drug could mean

either an NCE (New Chemical Entity) or a different dose of a previously approved drug, and such exclusivity offers market appeal for drug sponsors. At the same time, FDC products also appeal to patients because they provide a convenient and compliant means of dosing two drugs often taken together."

- Brad Gold, PhD, Vice President of Pharmaceutical Development, Metrics Contract Services



"The trend in the industry today is compatibility of both the active ingredients of a drug as well as its method of administration, ie, it must be 'patient friendly.' This is a direct reflection of a rapidly aging population and the rise in the home healthcare sector. In order to control costs and avoid cost-intensive therapies in a hospital or doctor's office setting, there is pressure to develop medicines that will enable more procedures in a private setting such as the home. Additionally, there is a rapid rise in therapies focused on conditions with small patient populations. These therapies, often 'Orphan Drugs,' are by US definition, drugs developed for treating conditions affecting fewer than 200,000 persons."

- Claudia Roth, Vice President, Innovation Management, Vetter Pharma International



"We are living in the era of transformation. Formulations using 'nanoparticles' as a part of targeted drug delivery are expected to enter the market in the next 5 to 10 years. Nanoparticles can help in the controlled release of a drug, and may also deliver two different types of drugs at the same time, to give a

stronger combination therapy, thereby increasing the efficacy of the drug."

- Dr. Siddharth Dutta, Frost & Sullivan Life Sciences & Healthcare Industry Manager



"High-throughput solubility screening along with advanced thermodynamic modeling can help predict the solubility behavior of APIs. This creates an opportunity to perform dosage form selection in the early phases of drug development."

- Irena McGuffy, MS, PharmD, Director, Formulations Development, Catalent Pharma Solutions