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The Science & Business of Pharmaceutical and Biological Drug Development

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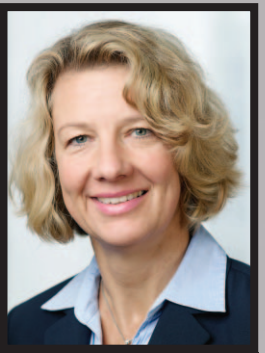

INTERVIEW WITH

HERMES PHARMA'S

HEAD, STABILITY TESTING & SENIOR QA MANAGER GCP

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HERMES PHARMA

HERMES PHARMA

Get the dose right®

HERMES PHARMA: Reducing Risk, Speeding Development - A CDMO Model Including GCP-Sponsorship to Better Meet the Needs of Pharma Companies

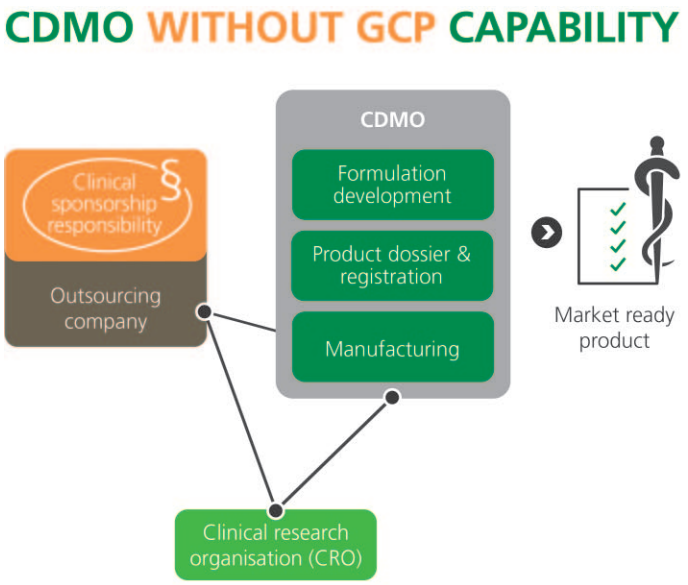
Developing and bringing a new, innovative oral medicinal product to market has always been challenging. To streamline the process, pharmaceutical companies have long sought the expertise and partnership of experienced contract development and manufacturing organizations (CDMOs).

Now, however, the landscape is changing. Pharmaceutical companies are increasingly requesting deeper CDMO support across the whole product development journey. As a result, new service offerings have emerged.

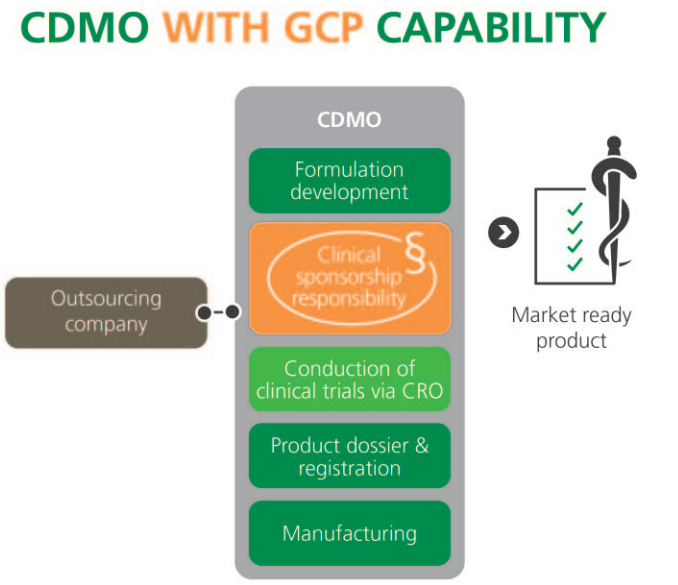
Drug Development & Delivery recently interviewed Dr. Martin Koeberle, Head of Analytical Development & Stability Testing, and Dr. Bernice Wild, Head of Stability Testing and Senior QA Manager GCP, at HERMES PHARMA, to find out more about the challenges of developing innovative oral medicines, as well as how these new service offerings are helping meet a critical need among companies looking to bring portfolio-enhancing formulations to market.

Q: What are the challenges of bringing new, advanced oral medicines to market?

Dr. Koeberle: This task is no easy feat — companies must ensure their new formulation is stable, bioavailable, soluble, and safe, which requires deep expertise and considerable resources. On top of that, it's an inherently risky process with high



The legally required function of **clinical sponsorship responsibility** is with the **outsourcing company**



The legally required function of **clinical sponsorship responsibility** is with the **CDMO**

failure rates, and competition is fierce, so timely development and rapid release to market is critical.

As if that wasn't difficult enough, though, there's growing market pressure for manufacturers to develop more user-friendly oral dosage forms — patient-centric formulations that are easy to swallow, convenient and pleasant to take, and that integrate well into busy modern lifestyles. While user-friendly oral dosage forms offer a wealth of benefits for pharmaceutical companies — deeper brand loyalty, new opportunities to better capture market share, and differentiation in a crowded marketplace — they are inherently more complex to develop and manufacture. For example, they often have more demanding stability and taste-masking considerations, requiring specialist technologies and know-how to get right.

Q: What role do CDMOs play in helping companies overcome such development and manufacturing challenges?

Dr. Koeberle: CDMOs have been — and will continue to be — a critical part of the pharmaceutical development ecosystem, supporting and enabling pharmaceutical organizations of all sizes.

Because CDMOs have such a breadth and depth of expertise, they can often advise on the most efficient routes ahead while foreseeing — and helping avoid — potential stumbling blocks. Ultimately, this translates to more cost- and resource-efficient pharmaceutical product creation.

Importantly, when it comes to time- and resource-strapped pharmaceutical companies, partnering with a CDMO isn't just a benefit, it's often a necessity.

Q: What trends do you see in the CDMO landscape? How are customer demands evolving?

Dr. Koeberle: As noted previously, a larger number of pharmaceutical companies are now turning away from what was once considered the "gold standard" of oral dosage forms — tablets and capsules — to more patient-centric alternatives, such as orally disintegrating granules, effervescent tablets, and instant drinks. After all, around half of people struggle to swallow conventional oral formulations, or just generally find them unpleasant to take. Naturally, that's creating a new space for CDMOs with the expertise to develop and manufacture such user-friendly products.

Critically, at the same time, pharmaceutical companies are more frequently requesting greater support with the clinical aspects of bringing an innovative oral formulation to market.

Q: What makes Good Clinical Practices (GCP) sponsorship such a challenge for pharmaceutical organizations, specifically?

Dr. Wild: While many pharmaceutical companies outsource clinical trials to contract research organizations (CROs), they must still bear the burden of GCP sponsorship. And that comes with a host of responsibilities.

For example, according to ICH Guideline E6(R2), sponsors must have a system in place to manage quality throughout the

clinical study lifecycle. While single tasks can be delegated to CROs as subcontractors, legal responsibility for clinical trial quality and integrity ultimately reside with the sponsor. In practice, that means sponsors must keep on top of a considerable list of duties, including maintaining a Quality Assurance (QA) system with written standard operating procedures (SOPs), ensuring compliance with these SOPs, qualifying contractors, conducting complex audits, serving regulatory GCP inspections, managing deviations and corrective actions and preventive actions (CAPAs), and managing and archiving the considerable documentation associated with that.

Q: How are CDMOs stepping up to meet this growing need?

Dr. Wild: CDMOs with an ear to the ground are aware of this growing need amongst pharmaceutical companies. And a few have stepped up to meet it.

As a result of this growing need, we're now seeing new service offerings emerge needed to bring advanced oral medicinal products to market. This includes GCP sponsorship to perform clinical trials for efficacy or bioequivalence proof. In the end, customers simply buy registrations for the final, successfully developed products, which are ready to be marketed.

Q: What are the benefits of a GCP-capable CDMO for these pharmaceutical organizations?

Dr. Wild: The benefits of this approach are hard to overstate. First and foremost, this type of CDMO offering means customers no longer need to take on the legal responsibility of clinical study oversight required by ICH E6(R2). They therefore don't need to have deep scientific and regulatory knowledge in clinical trials, create and/or maintain a complex QA system, reserve capacity to keep sponsor oversight, and train their staff in clinical trial regulations and requirements.

With a CDMO that has the expertise and ability to handle all aspects along the value chain, customers also get a true "one-stop shop" offering. Working with a one-stop-shop provider simplifies program management for the customer, as they no longer need to liaise with multiple service providers. Because this offering typically shortens drug development timelines, it can also offer a larger, industry-wide benefit — helping to get new medicines to patients more quickly.

Importantly, a CDMO that takes on program-wide responsibility, including shouldering GCP responsibilities and the risk of clinical trials, may have a deeper incentive to ensure product success. For example, customers could get a more targeted formulation development that takes all aspects of product creation into account (including clinical and regulatory considerations), for example.

Customers can reap another benefit too — that of operational efficiency and flexibility. Unburdened by large organization structures and processes they can expect streamlined project management and logistics, and a greater capacity to adapt to changing program requirements. And that could ultimately mean a more cost-efficient and faster time-to-market for your product.

Q: Can these GCP-capable CDMOs help meet the growing need for user-friendly dosage forms too?

Dr. Wild: Absolutely. Some full-service GCP-capable CDMOs specialize in the creation of user-friendly products, using their knowledge in development, manufacture, and testing to deliver market-ready products for pharmaceutical companies to purchase.

A CDMO with deep expertise in, and responsibility for, every step of the creation of user-friendly oral medicines can really de-risk a program by optimizing early steps with later development steps in mind. Take in vitro dissolution assessments and in vivo bioequivalence testing, for instance, which can be particularly challenging in the case of user-friendly oral dosage forms. Knowledgeable full-service CDMOs can maximize chances of study success by carefully tailoring formulation development with those testing requirements in mind (rather than settling for a formulation with good physical and chemical properties alone). Knowledgeable partners can also optimize bioequivalence study strategies in other ways, for example, by selecting the most promising reference product and taking regulatory approaches and constraints into account.

Importantly, the benefits aren't limited to pharmaceutical companies. Yes, such CDMOs unlock a reduced risk, streamlined path to getting user-friendly products into your portfolio. But more importantly, there's a knock-on effect also for patients — with fewer barriers to the creation and commercialization of patient-centric medicines, an ever-greater number of patients can access oral medicines that put them and their needs first. And that's something to celebrate. ◆