Partner with us today

BD Medical–Pharmaceutical Systems is a global leader in innovative, high-quality and customized drug delivery systems that include prefillable syringes, self-injection systems and safety and shielding solutions.

Furthermore, BD has a long history of leadership and innovation in the drug delivery industry. We are proud to partner with 27 of the Top 30 pharmaceutical companies[1] and our products are used by more than 500 pharmaceutical and biotechnology companies globally.[2]

For more information, contact **TechnicalServices_BDMPS@bd.com.**

References
1 IQVIA-based analysis & BD internal systems (SAP ECC, SAP Legacy, Tracis, Nodum), 2016 update.
2 SAP Legacy, Tracis, Nodum, January 2018.

The combination product challenge

As worldwide regulations for combination products evolve and Health Authorities' expectations grow, the need for a knowledgeable and responsive partner becomes increasingly important.

BD will help you overcome some of the biggest challenges during the combination product journey, such as:

- Establishing appropriate product knowledge and conveying it to governing agencies
- Demonstrating performance of the combination product as an integrated system
- Accessing important data ad-hoc, in a timely manner to ease the preparation of regulatory filing and Health Authorities' review processes
- Developing and implementing effective design transfer processes
- Creating business processes and quality systems to manage and guide a complex range of scenarios to support combination products

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Service offering

BD Medical–Pharmaceutical Systems

Discover the confidence of working with the right service partner

BD offers a broad range of value-added services spanning the entire development cycle. Engaging our experts ensures your drug is in the optimal delivery solution and increases your chances of a successful launch through:

Analytical testing

Ensuring long-term compatibility and stability of your drug product in the delivery system
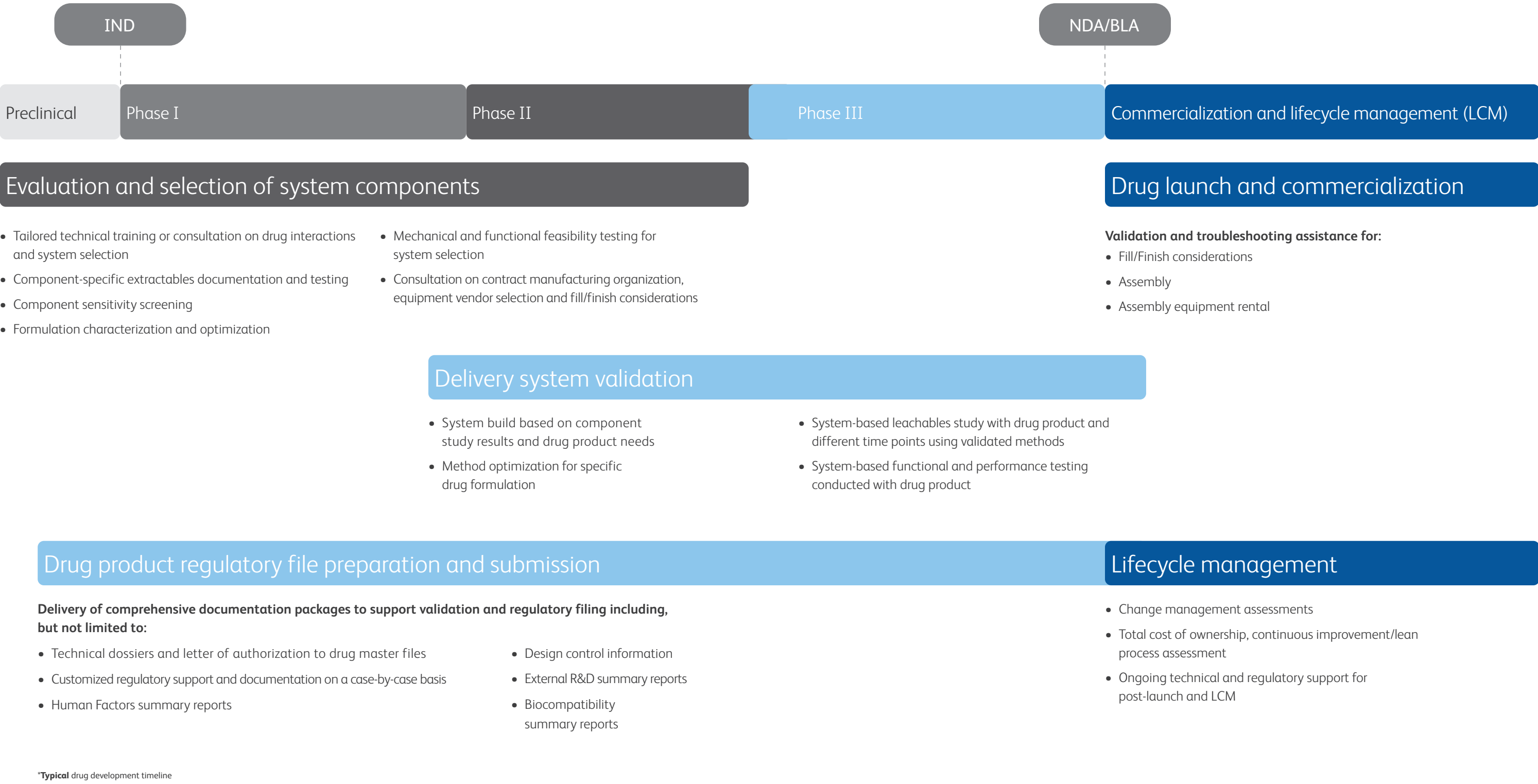
Fill/finish services

Such as not-for-human-use filling at our GMP laboratory, assembly and equipment rental and consultation on CMO/vendor selection

Medical affairs support

Including product safety, toxicology data and human factors data, which may be leveraged for official filing submissions and for meetings with regulatory agencies

Combination product testing and support

To help you navigate the rapidly evolving regulatory landscape quickly and effectively

Regulatory affairs support

Including technical documentation packages, electronic dossiers and other tools that can be customized on a case-by-case basis to help you successfully file with relevant governing bodies

What we offer

Access to technical and regulatory data packages

A tailored, consultative approach to providing services

World-class expertise in delivery solution selection and validation

GMP-compliant lab(s) with state-of-the-art equipment

Protocols that can be customized or developed to fit your specific needs

What you can gain

Reduced time to market as a result of faster availability of necessary information

Flexibility to choose as much or as little service as required, **saving time and money**

Confidence that your delivery solution is optimized for your drug product

High-quality test results that can be leveraged in regulatory filings

Assurance that your results will be relevant and **accurate**

Right solutions—right time

Expert capabilities at each stage

With 30+ years of providing support services, our team understands the drug development timeline and knows the best way to align it with key service offerings

IND

NDA/BLA

Preclinical	Phase I	Phase II	Phase III	Commercialization and lifecycle management (LCM)

Evaluation and selection of system components

- Tailored technical training or consultation on drug interactions and system selection
- Component-specific extractables documentation and testing
- Component sensitivity screening
- Formulation characterization and optimization
- Mechanical and functional feasibility testing for system selection
- Consultation on contract manufacturing organization, equipment vendor selection and fill/finish considerations

Drug launch and commercialization

Validation and troubleshooting assistance for:
- Fill/Finish considerations
- Assembly
- Assembly equipment rental

Delivery system validation

- System build based on component study results and drug product needs
- Method optimization for specific drug formulation
- System-based leachables study with drug product and different time points using validated methods
- System-based functional and performance testing conducted with drug product

Drug product regulatory file preparation and submission

Delivery of comprehensive documentation packages to support validation and regulatory filing including, but not limited to:
- Technical dossiers and letter of authorization to drug master files
- Customized regulatory support and documentation on a case-by-case basis
- Human Factors summary reports
- Design control information
- External R&D summary reports
- Biocompatibility summary reports

Lifecycle management

- Change management assessments
- Total cost of ownership, continuous improvement/lean process assessment
- Ongoing technical and regulatory support for post-launch and LCM

*Typical drug development timeline

We work with customers to provide the right solutions at the right time