
DS™
INPHARMATICS
ONE PARTNER
MULTIPLE CMC &
REGULATORY SOLUTIONS

We offer not just advice

We supply actionable strategies

Execution of strategies

And

Management in the trenches

"If I had asked people what they wanted, they would have said faster horses."
Henry Ford

WHO WE ARE

Who We Are:

- A Deeper Department.
  - Set up as consulting firm that serves the needs of small emerging biotechs, most of whom do not yet have major products approved
- Over 10 years in business, profitable and growing
  - 125+ clients throughout the US and Europe
- 30+ senior technical/regulatory consultants
  - Hands On, Deliverable oriented
  - FDA/EMA Regulatory and CMC operations expertise

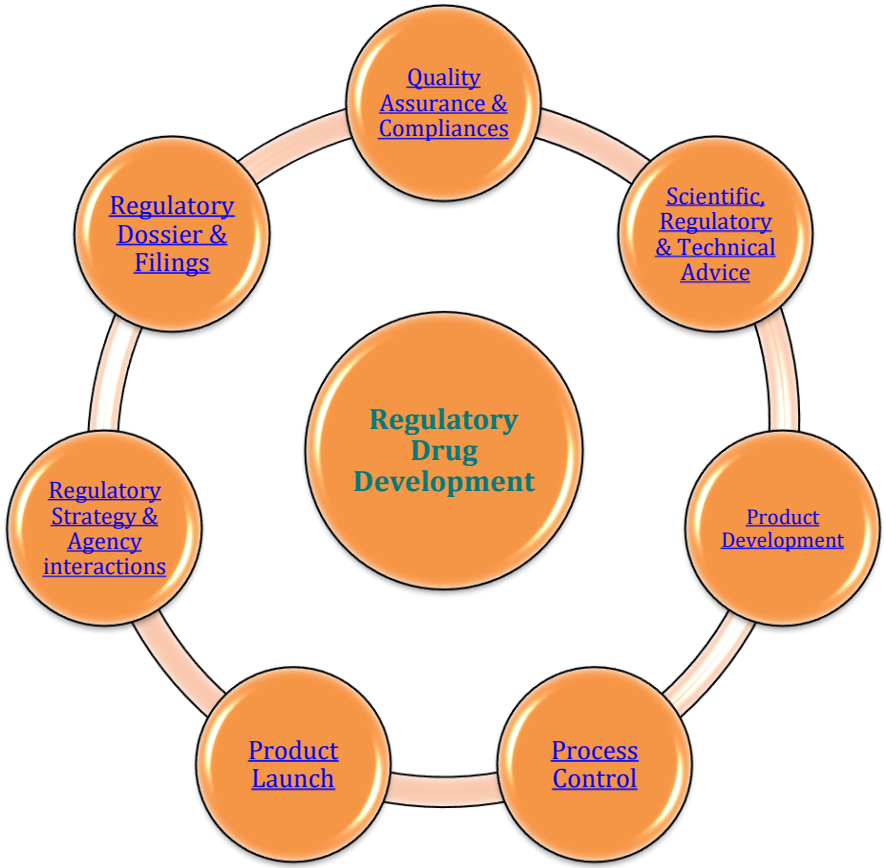
How We Help

Integrated Regulatory Drug Development Approach

Quality Assurance & Compliances

Regulatory Strategy & Agency interactions

Regulatory Dossier & Filings



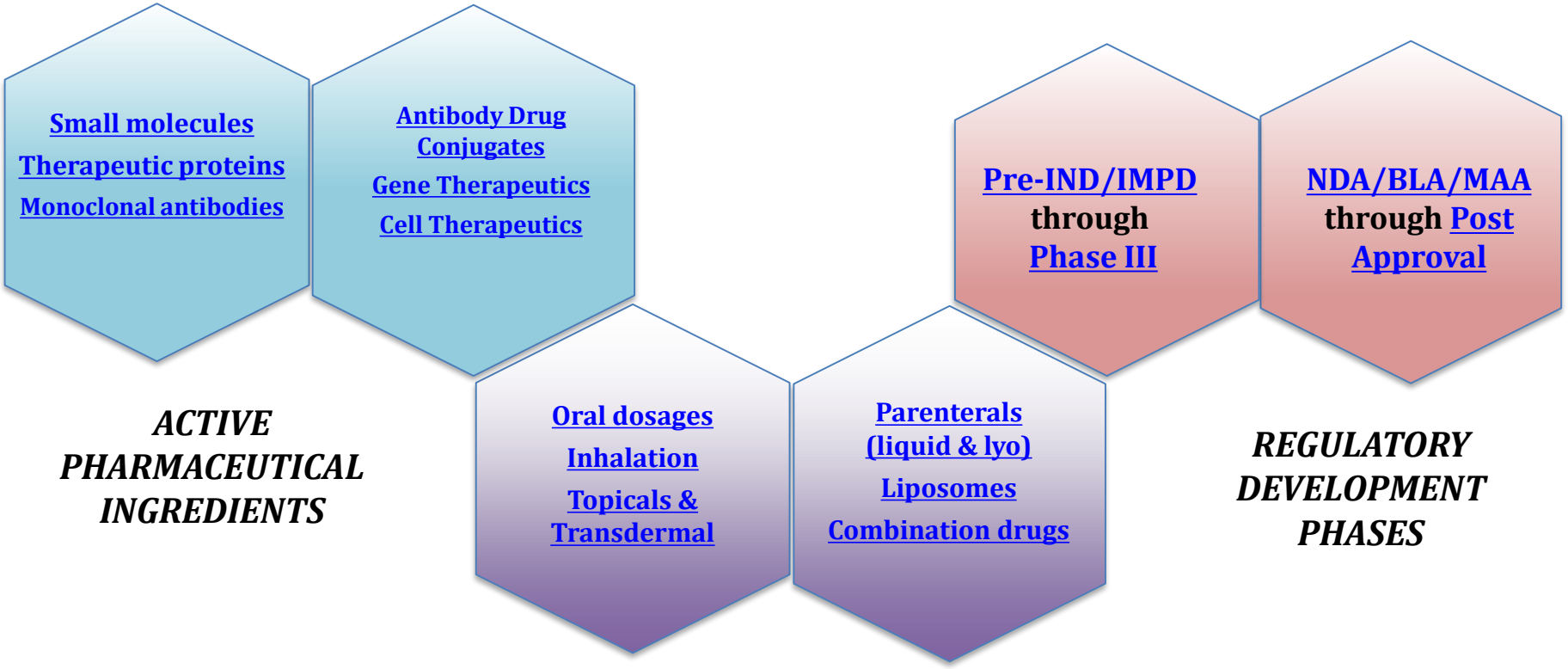
Scientific, Regulatory & Technical Advice

Product Development

Process Control

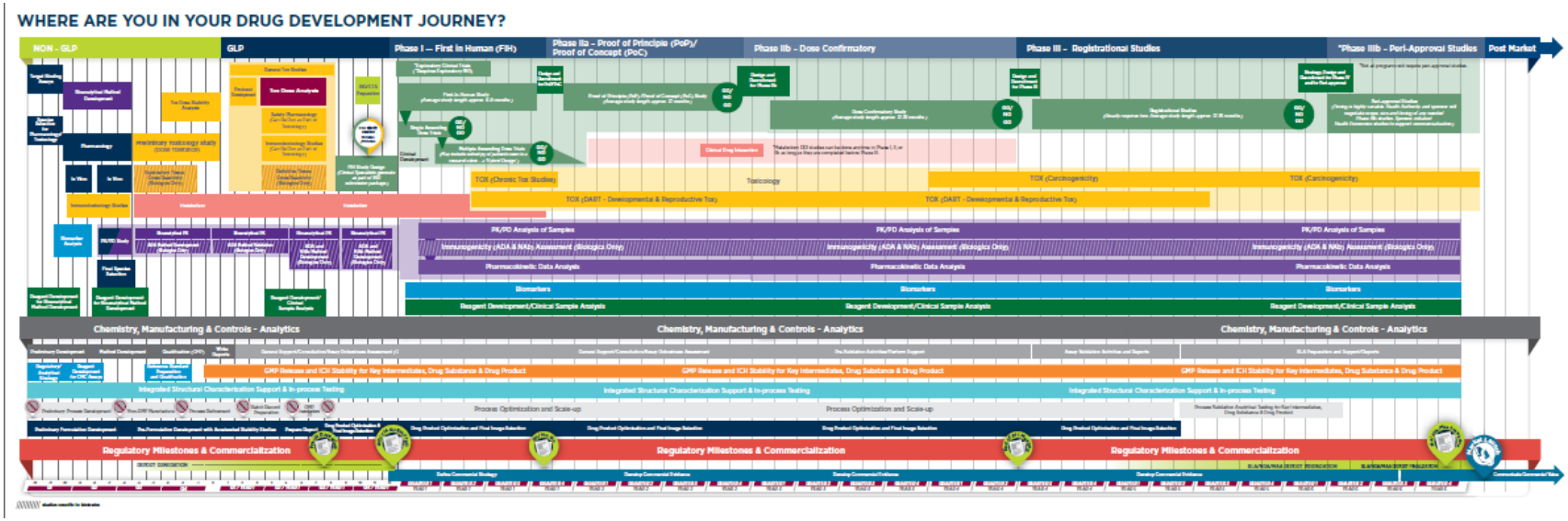
Product Launch

We can handle whatever you throw at us



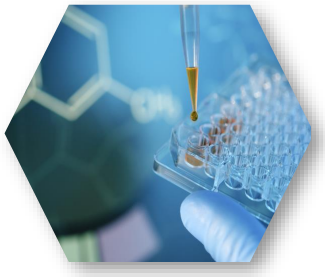
DSI can drive your product development program from **IND enabling through Approval** and beyond

Our expertise covers all major regulated therapeutic dosage forms and actives



Our teams of specialized **Subject Matter Experts** have years of bench-level and management experience to ensure accurate assessments, risk analyses and identification of strategies that provide a streamlined, **more efficient path to regulatory approval** that avoids often seen pitfalls and delays.

OUR DIFFERENTIATORS



All the expertise you need under one roof .

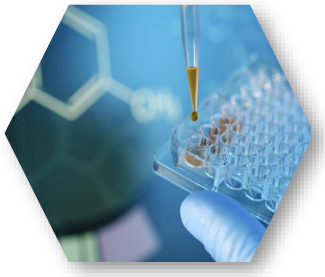
– There is no need to hire multiple consultants. DSI has all the expertise you need to advance your product development and regulatory approval programs.

Breadth of experience.

– DSI helps clients develop many types of regulated products. We have worked with companies to develop and obtain marketing clearance for drugs, and biologics in many therapeutic areas, including oncology, cardiovascular disease, metabolic disorders, and neurology.

Flexibility and responsiveness.

– We understand our client's need to reach company goals quickly. We are there when you need us and can provide a quick answer to a question or full product development support.



Deep knowledge of regulatory expectations.

– Our understanding of regulatory expectations comes from knowledge gained from experiences with other clients, products, and regulatory agency interactions.

Professional, experienced consultants.

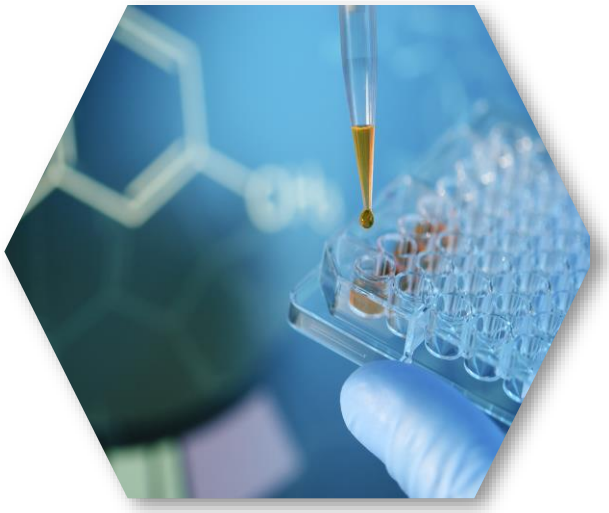
– DSI's staff includes technical, and regulatory professionals, with more than 20 years of experience in product development and marketed product support. DSI's consultants have worked with FDA regulators in CMO's and pharmaceutical and emerging biotech companies.

We are science-driven.

– Our multi-disciplinary teams of drug development, manufacturing, quality, and regulatory affairs specialists have years of real time experience and are trained to evaluate risk.

We combine drug development with regulatory affairs expertise.

– This ensures that CMC programs deliver the data and information required to meet review expectations for each stage of clinical development.



We can partner with you in several ways.

- Our cross-functional teams can drive your drug development programs to success from start to finish, offering smarter, more efficient ways to streamline the process.
- With our Subject Matter Experts, we can fill specific, in-house knowledge gaps with targeted solutions.
- We can provide process driven Products to help in some of the most common areas of need.

We offer you a unique combination of drug industry experience with a team of career Subject Matter Experts

- Our CMC specialists have a proven track record in the development and commercialization of small molecule and biological products.
- Our regulatory experts have created submission content and employed field-tested agency communication strategies for varied dosage forms.
- Our people have worked under tight budgets, solving problems in creative ways.
- We have the bandwidth to react quickly and efficiently to meet your needs.
- We supply your internal team with a deeper bench that they can draw from as needed.

We take a team approach:

- We offer you a clear focus on development and regulatory strategy from a multi-disciplinary team of experts.
- As projects evolve, so do we, bringing in the right experts to address new questions on an as needed basis.

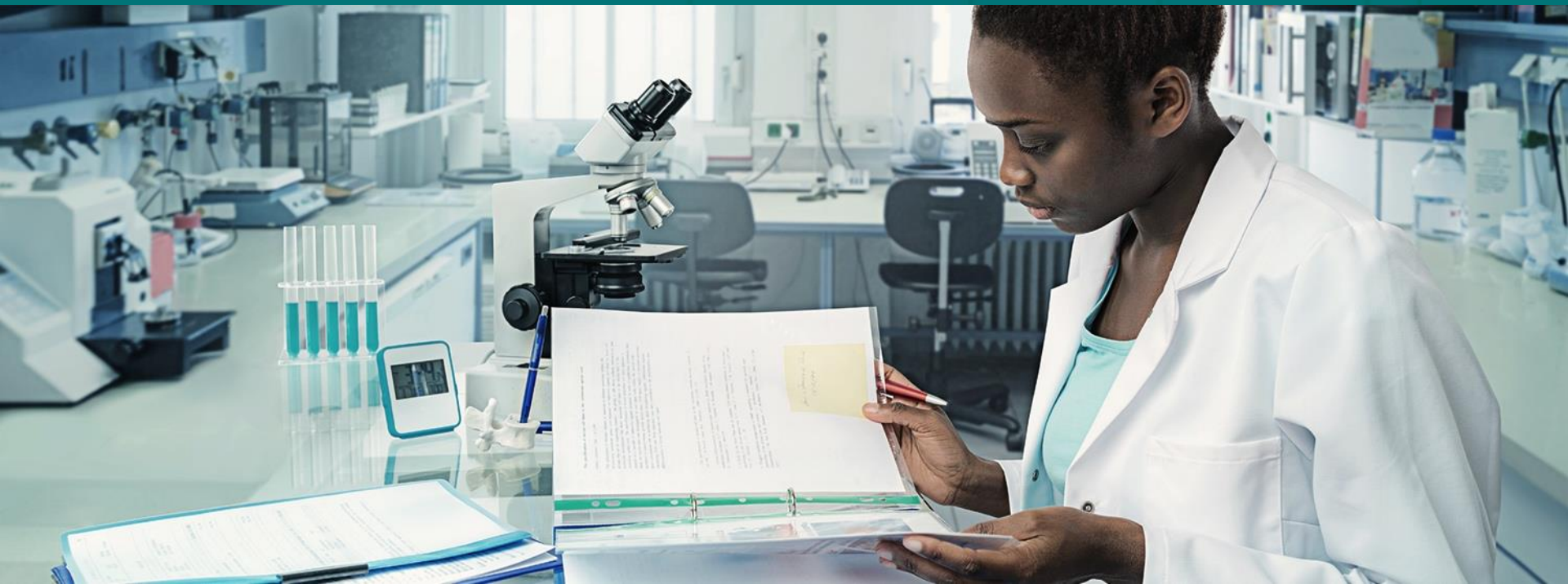
✓ Our multi-disciplinary teams eliminate the need for clients to find and manage multiple consultants.

✓ Our central planning group involves the necessary disciplines at the right time.

We have just one point of contact for every team

- While we value the minds of many, we appreciate the simplicity and efficiency of one point of contact.
- This ensures a seamless process, exceptional communication and an unmatched customer experience.

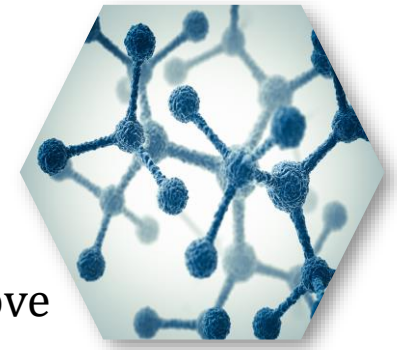
OUR EXPERIENCE



Our Experience:

- DSI has a long track record of success on projects of varying scale and complexity.

- A history of taking pride in our:
  - Ability to supply comprehensive risk based common sense answers to our clients needs.
  - Quick response to our clients' often urgent requests.
  - Meeting crucial milestones and tight deadlines.



- DSI has proven itself as the industry leader in helping clients move quickly and efficiently through development to regulatory approvals.

We can prepare you for your next regulatory submission

- Provide regulatory and technical review to select the best filing strategy.
- Supply critical content decisions to produce effective and compliant investigational and marketing submissions for the US and EU.
- Author Module 2 and 3 CTD content.
- Prepare for FDA/EMA meetings and manage regulatory agency interactions.

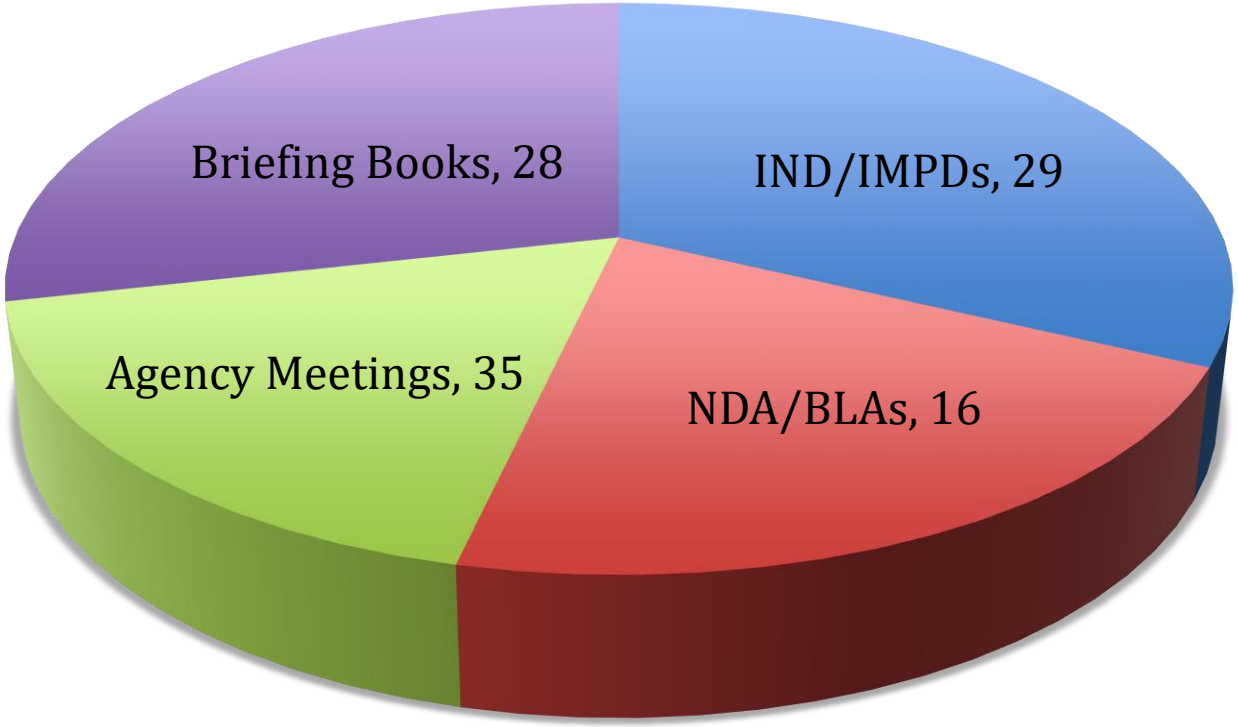
Recent regulatory highlights:

- EMA and FDA Liaison
  - Guidance Interpretation
  - Recent Pre-IND, End of Phase 2 question development
  - Agency Meetings — Attendance, Interactions, Discussion, Conclusion, Commitments
    - Agency Briefing Books for pre-IND, EoP2 and Pre-NDA milestone meetings
    - Strategy, preparation and review of FDA and EMA submission reviews
- Regulatory Submissions
  - (Investigational) IND and IMPDs
  - (Marketing) NDA, BLA and DMFs
    - CTD Quality Modules 1 and 2 and Development Reports supporting:
      - 505(b)(1), 505(b)(2) and 505(J) filings
      - Expedited Development Programs (Breakthrough Therapy Designation)

Recent regulatory highlights.

- 2 NDAs (approved in 2017)
- 2 NDAs, 1 BLA (filed in 2017)
- 3 NDAs,1 BLA, 1 NADA (completed but not yet submitted, in process)
- 5 new IND and IMPDs, 20+ updated and maintained (CMC info Amendments)
- FDA Expedited Development Meetings, (Breakthrough Therapy Designation)
- Complete Response Letter response for approval of surfactant
- Strategy, preparation and review of EMA issued Day 180 questions for recombinant peptide
- Development reports and NDA to support drug-device combination 505(b)(2) filing
- Agency Briefing Books for pre-IND, EoP2 and Pre-NDA milestone meetings

100+ Regulatory Interfaces.



Recent CMC highlights.

- Contacted by “Breakthrough Therapy” client late on a Friday afternoon. Team of 4 SME’s flew to west coast on Sunday for an onsite Gap assessment beginning on Monday AM.
- DSI’s oldest client went into cash reserve mode for 4 years at the 4th year mark in our relationship. Once funded project restarted at breakneck speed to file NDA while requiring Phase 3 Development work to be done in parallel. After being client for 10+ years DSI successfully filed NDA that has recently been approved in US.
- Managed all of CMC development and operations, CMC Regulatory and QA for a client looking to move a small molecule quickly through phase 1 as proof of concept. Project completed for recent successful out-licensing
- Manage multiple disparate projects, Liposomal, Radiolabeled protein, Oral tablets, Preclinical oncologic, Internal Factory design-build, in conjunction with existing outside consultants, for large corporate entity

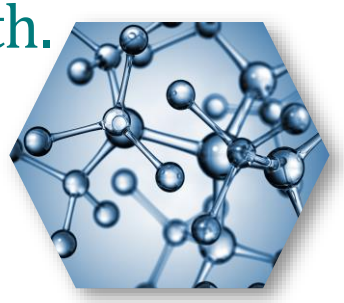
IN SUMMARY

Are you developing a pharmaceutical drug product for commercial distribution or are you just doing Process R&D?

- DSI can provide teams to drive your product development program from start to finish.
- DSI can be your deeper department and fill in-house CMC expertise gaps on a project basis.
- We provide expert CMC regulatory drug development assistance for companies that are in business to do business and succeed.

PARTNER WITH US

- For pharmaceutical and biopharmaceutical companies with products in development, DS InPharmatics is the CMC Regulatory Development company to partner with.
- We want to be part of your success in long run.
- Our team of specialized CMC experts has real-world experience. We expertly assess risks, produce strategies, execute and support plans that ultimately steer your regulatory pathway to success.



Enough about us..

We would love to hear more about your company…

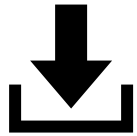
What's exciting?
What are your challenges?
What keeps you up at night?
Where do you feel the pressure of time and recourses?

Where could you use some help?

Extra Slides

Quality Assurance and Compliance

- Quality Systems and SOPs
- cGMP Compliance & Audits
- Quality and Risk Management
- Quality Agreements
- Vendor Qualification
- Mock PAI



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Case Study QP (Qualified Person) Audit and EU CTA

Challenge - A first-in-man clinical study was intended to be conducted in the UK and had three US CMC contractors. The dosage form was a PIC (API powder in a capsule). The EU clinical CRO had difficulty coordinating the manufacturing and import licenses and the inspections of the US manufacturing sites with a contract QP.

Response - The PIC activity was transferred to a UK CMC CRO with an in-house QP. The CMC consultant's early discussion with the QP facilitated API supply, analytical methods transfer, PIC manufacturing, and packaging and labeling in compliance with both US and EU GMP.

Outcome - The elimination of QP audits of the US manufacturing and packaging contractors shortened the time frame for the preparation of clinical supplies and allowed an earlier start to the clinical study.

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Regulatory Dossier & Filings

- The CTD Module 3 & Module 2, QOS
- Briefing Books
- IND's, NDA's, BLA's DMF's
- CMC Submission Authoring Experts

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Scientific, Regulatory & Technical Advice

- US FDA and EU EMA advice and guidance
- RSM to Final Drug Product planning, advice and management
- Future Trends, Biosimilars, Cell and Gene Therapy areas
- Lifecycle Management for Drug Products
- Due Diligence for In/Out Licensing or M&A
- “Phase Appropriate Advice” for all stages of product development

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Case Study – Preserving the Historical Tox and Clinical Database for an Inherited Drug

Challenge - Two compounds (one oral, one IV) had been in the clinic in Europe ten years prior with academic sponsors and research CMC supplies. Each was being re-positioned for the current US oncology market. The solid dosage form API was extremely water insoluble and required high dose levels (250-1200 mg). The historical dosage form used in the European clinical trials was an unformulated PIC (powder in a capsule) where the API had a purity of >99.7%. The IV product was unstable in aqueous solution where only a rudimentary freeze-dried product was used previously. This API had high (~5%) levels of starting materials and impurities. The sponsors of both compounds wanted to preserve the existing historical tox and clinical database.

Response - DSI reviewed the CMC databases and found them to be deficient to standards. We designed and managed the necessary scientific studies, including pre-formulation, formulation development and analytical methods. DSI met with the FDA and presented the approach to future CMC development. Oral dosage form with the high purity API, was re-initiated into the clinic with comparable high purity API PIC, with a very lengthy and costly purification process. DSI optimized the process which was qualified with toxicology studies on the new API. For the IV dosage form, we reduced and/or qualified the existing impurities.

Outcome - Proposed approaches were discussed with the regulators at pre-IND meetings, DSI submitted new CMC sections in the UK and in the US which were approved for new phase 1-2 trials. The tox and clinical databases for both compounds were preserved.

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Regulatory and Agency Interactions

- Expedited Development Programs
  - FastTrack, Accelerated Approval, Priority Review
  - Breakthrough Therapy Designation
- Post Approval Change Control
- Agency Response Management and Interface
- Agency Meetings

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Product Development

- Analytical Development
- Stability Programs
- CTM Manufacture & Forecasting
- Process Development
- Formulation Development
- CQA's

Back

Process Control

- Process Optimization, DOE, CPPs
- Specifications/Methods
- Batch records and COA's
- RSM Establishment and impurity profiling
- Tech transfer and Facility startup
- Process and Method Qualification and Validation

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Product Launch

- Product Launch Preparation
- Supply Chain Establishment and Management
- COG's, Commercial Forecasting
- PAI Prep and Mock Audits

Back

Small Molecule Experience

- Performed expedited review and revision of 28 spike and purge impurity development studies performed by CMO that were deemed inadequate for clients regulatory filing
- Authored all synthetic route and process chemistry development reports for client culminating in acceptable NDA for NCE currently under review by FDA
- Acted as Person-in-Plant for process validation of X step synthetic process at European CMO for US based client
- Managed all API process development, tech transfer to new site, sourcing and manufacture for client moving quickly to NDA
- Established supply and definition of RSM for porphyrin molecule extracted from natural source where only global source went out of production. Presented and gained approval from FDA for plan to switch vendor. New supply source vetted, manufacture established, and filed in approved NDA

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Case Study 1 - API sourcing Issue

Challenge -

NDA drafted and awaiting filing when news of FDA Consent decree stopped Chinese supply of API. Vendor was already filed in draft NDA with near term filing date.

Response

Sourced and established new supplier
Coordinated change with client and FDA
Added new supplier into NDA

Outcome

New supplier acceptable to FDA
Filing delay was minimized
FDA accepted NDA and product under review
Product licensed to Big Pharma

Back

Case Study 2 - API sourcing Issue

Challenge -

Pre-IND candidate, API did not meet specifications

Response

Identified and executed process improvements
Reworked product
New CMO is engaged and given operations support

Outcome

New CMO identified
Increased yield in the API process
Lengthened client's cash burn rate
COG reduction thru increased yield
Shortened time to achieve key milestones
IND filed; Product licensed to Big Pharma

Back

Gene and Cellular Therapy

- At this time experts with hands on experience in these areas are few and far between as the fledgling field takes off. Most work has been done at the academic or research hospital level.
- In today's fast moving gene and cell therapy areas DSI has made the investment in thought leaders to help you through the Regulatory Development hurdles associated with new exciting areas where regulations are still lagging behind the science and commercial expansion.
- Early Regulatory exploration of genome editing technologies for therapeutic use. CRISPR, CAR-T.

Back

Monoclonal Antibody Experience

- DSI was hired by a developer of monoclonal antibody products to assist with general parenteral formulation questions. Gaining the clients trust and respect DSI increased responsibilities and supplied 6 SME's for multiple projects in the support of QA, Regulatory Affairs, Document Management, AR&D, Sterile Manufacture and finally authored Mod 2 and 3 of BLA. When company was acquired DSI was working on 4 new monoclonal antibody products. The project ran over 2 years.
- Worked with a west coast sponsor of a breakthrough monoclonal product to do a complete gap analysis of the proposed BLA filing and develop and manage a GANTT on requirements, resources and timing to complete authoring of BLA. Once gap analysis and GANTT complete DSI authored initial draft of BLA.

Back

Antibody Drug Conjugate Experience

- Review, comment, re-wrote draft Mod 3 sections of ADC BLA
- Performed batch record review, authored viral clearance study reports, defined DOE and established CPP's, generated process validation protocols and wrote scale up and development reports for phase 1-2 ADC product
- DSI is currently managing the process development, formulation, fill finish, analytical methodology, technology transfer and CTM supply chain for a radiolabeled ADC recombinant protein

Back

Therapeutic Protein Experience

- DSI is currently managing the process development, formulation, fill finish, analytical methodology and CTM supply chain for a radiolabeled ADC recombinant protein

- DSI SME functioned as clients “person-in-plant” overseeing three successful protein process validation runs at an Austrian CMO over the course of 4 months.

Back

Oral Dosage Experience

- DSI managed all CMC and QA aspects of the process development, formulation optimization, dosage form optimization and characterization, establishment of CQA's and CPP's, scale up, process validation, analytical methodology, validation, supply chain and QC for a recombinant peptide delivered in a enteric coated tablet.

- Authored 505b2 submission, in its entirety, for a tamper resistant opioid currently under review by FDA. DSI also managed the establishment of as discriminating dissolution assay for this tamper resistant polymer based product.

- Reviewed and revised process validation protocols in anticipation of managing, as SME "person in plant", client's coated tablet dosage form at CMO in Belgium.

- Re-started semi-solid oral cardiac drug in capsule project that DSI had previously worked on through NDA filing. Drug was now being pursued by a new sponsor and long shelved project had to be revived for new IND and CTM's for new clinical trials. DSI restored project with original team members from projects previous incarnation and proceeded to author new IND and manufacture CTM's.

Back

Case Study - Defining Packaging and Labeling Options for a Complex Titration Clinical Study

Challenge - The clinical group provided a proposed blister package design for a complex, global, up-titration maintenance and down-titration placebo-controlled study involving four stratifications of subjects. The titration phases involved six distinct ascending or descending doses, each of which had a matching placebo control. At any stage of the study, if there were minor side effects, a subject's dose could be reduced. The proposed blister card design required 14 different card layouts, with different amounts of dosage units, with labels in 6 languages.

Response – DSI recommended a single blister card layout which provided uniformity in the number of dosage units taken at any stage of the study and minimized the variations of time-consuming card design. Common static text was preprinted on the cards themselves, while dynamic text was provided in a booklet label.

Outcome - The lead time for the single card layout, pre-printed static text and booklet labels was reduced by 6 weeks. Costs of the modified approach were reduced by 25%.

Back

Inhalation Product Experience

- DSI authored Mod 2 and QOS, Mod 2, of NDA for inhalation drug device combination product ONZETRA™ Xsail™ (sumatriptan nasal powder), a New Treatment for Acute Migraine Using Bi-Directional™ Breath Powered® Technology which was approved in 2016.
- Sponsor of inhaled surfactant product received 6 non approvable letters from FDA. DSI worked with client's regulatory group to answer deficiencies in Complete Response letter. Product, Surfaxin™, was finally approved after 6 years.

Back

Parenterals (liquid & lyo) Experience

- DSI manages all aspects of recently approved pre-natal liquid parenteral injection and DP CTM completely through pipeline fill This product and the client were merged into a major pharmaceutical company. DSI still functions as the institutional knowledge base and Regulatory SME for questions regarding the product.

- We were tasked with maintaining CTM supply for a product that was showing signs of OOS trend for particulate matter in a parenteral. DSI successfully rectified a formulation complication causing precipitation of recombinant protein in a phase 1 clinical trial. We also reviewed data and made case for setting of appropriate particle specifications allowing current CTM to be utilized in the clinic until new material could be manufactured.

- For a phase 3 parenteral product we recently optimized the lyophilization cycle saving the sponsor from product failures but also decreasing COG's by decreasing cycle time.

- Recently, managed the transfer of 2 liquid parenteral products including project scoping, RFP's, Bid analysis, Transfer protocol authoring and execution, QA audit and CMO qualifications, method transfer and qualification, Stability protocol review and approval, aseptic operations assessment, batch record review, Engineering runs, CTM manufacture and IND update.

Back

Combination Drug Experience

- Small virtual company required DSI to write NDA for Inhaled drug/device combination product. During finalization of Mod 3 and QOS authoring the sponsor, our client, was purchased by larger European pharma company that then took over review and approval of NDA. DSI team worked with new product sponsor to bring them up to speed on the product history and present state going into the NDA. We then added multiple team members to meet their internal review revision requests. NDA was then finalized and filed under the tight timeframe due to change of control and new sponsor involvement.
- Authored Mod 2 and 3 for transdermal patch delivery of hormonal product.

Back

Case study - New Combination Product

Challenge – A virtual company conducted a cardiovascular clinical trial using two 30-year old, generically available oral solid dosage forms, dosed separately and together. The clinical data demonstrated that the two products in combination were dramatically superior to either drug alone. Their intent was to market a fixed dose combination product using the 505 (b)(2) NDA approval pathway. At the EOP2 meeting the FDA indicated that the only additional clinical trial that would be necessary for approval would be a BE study using the individual generic tablets versus the firm's formulated combination product. The identification of a clinical/commercial manufacturer and the formulation, analytical procedures, etc., for the combination product had not started.

Response - The CMC development plan was conceptualized in less than one week. CMC contractors for supplying both APIs, formulation and manufacturing prototypes of the varying doses of the combination product and for developing analytical methods reflecting contemporary regulatory requirements were identified, bid, awarded and qualified. Pre-formulation and analytical method development proceeded in parallel with the conduct of GMP compliance audits. Scale up batches were prepared and used for NDA stability and the BE study concurrently.

Outcome - The NDA was submitted 9 months after the EOP2 meeting containing 6 month stability data that was evaluated to project a 24 month expiry date. (This drug, Product X, was eventually approved.)

Back

Liposomal Experience

- DSI authored the Quality Modules, Mod 3 and QOS, Mod 2, for the recently approved NDA for the liposomal product, Vyxeos™
- Working with an Asian company on the product development of a startup liposomal product DSI has been responsible for management and executions of many CMC operation functions including equipment installations and qualification/validations, startup and engineering batches through CTM manufacture, specification establishment, CTM batch record review, COA review and IND authoring,
- In the last year performed Due Diligence review of in licensed liposomal product for potential purchase. Product was in licensed by client.
- Assisted in the technical process development of several liposomes and liposomal drugs

Back

Topicals & Transdermal Experience

- Brought in by venture capital firm to perform due diligence of current operating sponsor of transdermal patch combination product. DSI then assisted firm to update analytical procedures, establish process and compliance controls and finally authored the sponsors NDA for the product.
- DSI provided technical and regulatory advice to Asian firm looking to develop topical gel formulation of natural microbial product for the US market.

Back

Pre-IND and IND/IMPD Experience

- In 2017 DSI authored:
  - 2 small molecule IND's
  - 2 liposomal IND's
  - IMPD for phase 1 study in UK
- Currently authoring 2 IND's
- Client product was non-approvable for Clinical reasons and project stopped for 4 years. DSI team hired to manage all of CMC, QA and Regulatory. Team resurrected project and authored new IMPD for project for phase 1 EU Clinical trials
- US Drug Sponsor facing bankruptcy sold product to Canadian firm for the purposes of Canadian tax credits. In order to receive credits Canadian firm was required to diligently move product through proof of concept development. DSI assisted Canadian Sponsor in completing all required work and authoring IMPD to perform successful phase 1 study in EU culminating in sale of asset to yet another sponsor..

Back

Case Study 1 – Pre-IND meeting

Challenge

Client preparing for Pre-IND meeting with FDA. API and DP Development work performed by Multiple CMO's. Client lacked internal capabilities to address CMC issues or prepare Pre/IND documents

Response

Organized all process information from CRO's,
Prepared Pre-IND briefing package and attended meeting with Client and FDA
Prepared the CMC section of the IND

Outcome

FDA agreed to GMP starting materials as proposed
No CMC related questions requiring a response to the FDA
The IND was submitted and approved without any questions from FDA

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Phase 3 Regulatory Development Experience

- Development of regulatory strategies for synthetic and biologic products
  - Starting materials, genotoxic impurities, viral clearance
- Development, preparation and maintenance of regulatory submission
  - Missing Data, expedited programs, gaps in strategic decisions
- Guidance with FDA and regulatory health authority requirements, regulations and guidance
- Interactions, including information requests and meetings (e.g., pre-IND, end-of -phase 2, pre-NDA and pre-BLA)
- Support for pre-approval inspections of manufacturing facilities
- Development and maintenance of post-approval documentation (e.g., annual reports, Post-Approval Supplements (PASs), Changes Being Effected (CBE) and Type I and II variations)

Back

NDA and BLA Experience

- DSI authored and had 2 NDA's approved in 2017.
  - Vyxeos™
  - NERLYNX® (neratinib)
  - VNDA antibiotic for pets
- In 2017 DSI authored (under review):
  - BLA for a monoclonal antibody
  - NDA for new antibiotic
  - Stannsoporfin
  - 505b2 for a tamper resistant oral opioid product.
  - VNDA
  - IMPD for phase 1 study in UK
  - 2 small molecule IND's
  - 2 liposomal IND's
- Currently authoring one NDA, one 505b2 NDA, 2 IND's and sections of BLA

Back

Case Study 1 – NDA RTF (Refusal-to-File)

Challenge - This virtual company's first NDA was originally prepared by a small clinical CRO and was returned with a RTF letter. No new clinical data was requested; only an expanded analysis of the data. The FDA also requested that the firm provide substantial improvements to the organization of all the data. There were numerous CMC deficiencies; including missing quality attribute tests, inconsistent information between sections, inaccurate data treatment and insufficient stability data.

Response – Mod 3 was evaluated for compliance to current FDA expectations and data was identified to correct deficiencies. Scientific studies to provide the missing tests and data were defined, managed and summarized. Proposals to the Agency to allow the use of already manufactured batches for the generation of some of the new test data were based on science and precedent. The entire CMC section was streamlined and re-written.

Outcome - The re-submitted CMC section resulted in an approvable letter, thus salvaging a previously failed product.

Back

Case Study 2 - Successful FDA PAI (Pre Approval Inspections)

Challenge - Eight small, emerging pharma/biotech companies submitted their first NDA/BLA to FDA, listing a variety of CMC contractors. These CMC contractors included API manufacturers, analytical labs, clinical manufacturing groups, clinical packaging, labeling and distribution firms and were located in the US, Europe and Japan. Most of the contract organizations had never had a FDA PAI.

Response - The CMC consultant visited 15 manufacturing sites that had never had a FDA inspection. Each was evaluated for compliance to cGMPs for the specific operations they conducted for their clients. Deficiencies were identified along with options for corrective action. The CMC consultant worked with the virtual companies and many of their CMC contractors to monitor progress of the various upgrades and improvements to systems and operations.

Outcome - Each of the 15 manufacturing sites passed their first FDA PAI. (Note that the overall rate for FDA turndown is 15-20% and about 50% for first-time inspections).

Back

Post Approval Experience

- DSI managed product launch for virtual company focused on marketing. We managed all operations of supply chain and distribution including release, QA systems, sourcing/startup and NDA supplement for physicians samples, bioequivalence report supplement, NDA filing change control and compliance and life cycle management.

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