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Welcome to the SOLIQS

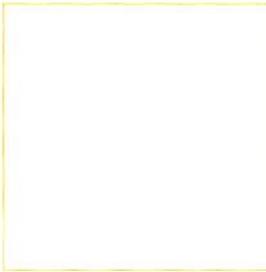
SOLIQS is a leader in drug delivery with marketed products and a proven track record in enhancing the bioavailability of poorly soluble compounds using its platform technologies [Meltrex®](#)

SOLIQS will take all efforts to provide customized solutions and give you consultative support to your situation.

SOLIQS Technology Platform Offers:

- Novel oral dosage forms for compounds with solubility challenges or that require specifically designed release profiles
- Improved clinical profiles (safety, efficacy) and patient compliance
- Reducing pill burden to patients
- Minimized food effect and/or gastric irritation
- Reduced intra- and interpatient variability
- Significant reduction in dose while maintaining therapeutic efficacy
- Increased R&D productivity and throughput
- Solvent free process with GRAS approved excipients

SOLIQS provides "Solid Solutions for Insoluble Substances"®



Up-to-Date Information

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Project Structure

Each project is structured to meet the needs of the client company and costed accordingly. However, typically a project might proceed as follows:

Phase I – requirements for Clinical Trials (CT) Transfer of a selected lead formulation to pilot scale or larger equipment. Manufacturing trials to define process parameters, cleaning verification, etc. with a further analytical program which could cover drug potency/purity, content uniformity, dissolution testing, drug crystallinity including analytical method validation.

As a next step we could go forward with manufacturing a pre-batch based on manufacturing process and formulation composition.

The pre- batch provides the supportive data which are necessary for finalization of the manufacturing instructions needed for CT manufacturing. Preparation of batch records and manufacturing of the clinical batch itself is generally performed meeting current GMP standards.

CT samples can be provided to our customers as either bulk material or fully packaged material for the clinical studies, together with the required stability testing, clinical lot validation and release testing by Quality Control.

Our team could also help you in compiling the Investigational Medical Product Dossier (IMPD) and Investigational New Drug (IND) Application.

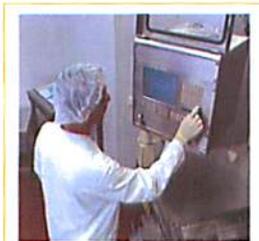
Following successful results of the Phase I (or Proof of Concept) study we would start with up-scaling the manufacturing process in pilot-plant scale (*usual batch size 25-100 kg*) or production scale (*> 100 kg*) including samples for Phase II/III studies.

Phase I Scale-up for clinical trial batches (phases II and III)

The development trials support the characterization of the manufacturing process and define any critical processing parameters. These data would provide the basis for further scale-up and necessary adjustments (*SUPAC – Scale-Up & Post Approval Changes*).

In the subsequent Development Phase the process parameters will be defined for manufacturing instruction, for the production for registration batches. Long-term stability data will be generated based on the registration batches.

- Registration batches would be manufactured on production-scale equipment and the results summarized in a Development Report.
- Finalization of process parameters for full-scale production prior to manufacture of validation batches and subsequent market supply.



Operator and display system

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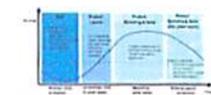
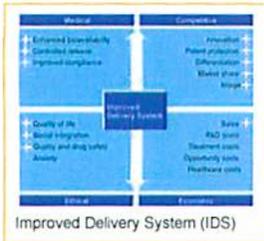


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Improved Delivery Systems (IDS)

There are many recent examples, such as ZANTAC® (*ranitidine*) and PROZAC® (*fluoxetine*), where generic products have entered the market very soon after the basic patent protection expired. Whilst it may be possible to develop a single isomer to replace a racemic original product, in the way that AstraZeneca has substituted *esomeprazole* (NEXIUM®) for *omeprazole* (LOSEC®), this is not always possible. Reformulating the original product with a new and innovative technology can be very successful. The classic example of this was Pfizer's billion-dollar product PROCARDIA XL®, a once-daily formulation of the established but ageing *nifedipine*. Enhanced convenience and resulting improved compliance may result from these technology or formulation switches. Another form of improved Delivery Systems is to develop a product with an improved pharmacokinetic profile which leads to advantages in the therapy and is a benefit to the patients. It is never too early to start implementing an Improved Delivery Systems strategy, particularly with the long lead-times for the development of a pharmaceutical product.



Lifecycle strategies for pharmaceuticals



An effective Improved Delivery Systems (IDS) strategy can address these challenges by **enhancing** products to **expand** use and **extend** product life.

SOLIQS's Meltrex drug delivery technology can help to extend your product's life by providing:

- enhanced bioavailability and therefore reduced drug load
- unique pharmacokinetic profiles from fast release to once-daily sustained release
- unique and difficult to copy (*to prevent counterfeiting*) solid dosage forms, such as caplets, lenti shapes and sometimes even transparent ones!
- molecular dispersions ("*Solid Solutions*") to overcome bioavailability and other problems related to polymorphism.

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Solid Solutions for Insoluble Substances®

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SOLIQS provides Solid Solutions for Insoluble Substances®

SOLIQS, the global drug delivery business of Abbott GmbH & Co. KG applies its formulation expertise to its customer's compounds, focusing on **increasing the bioavailability** of poorly water soluble compounds, as well developing **specifically designed release profiles**.

From the start of a cooperation, SOLIQS dedicates resources to its partners' projects, including nominated personnel from project management, formulation and analytics. This team will accompany the project during the definition of the work program, the finalization of the development agreement, through to the execution of the program.

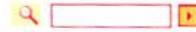
During the program we make sure that we communicate the progress of the activities on a frequent basis. We know that each project has to be handled based on its specific characteristics and it is our aim to merge the partner's knowledge of the compound with SOLIQS's technology expertise to achieve the target profile, meet quality expectations and stay within agreed time and budgets plans.

SOLIQS has had over 10 years of experience in partnership success with this approach. We are currently collaborating with many of the leading pharmaceutical companies in carrying out development programs and commercial manufacture with their drug substances, and we are always interested in talking to potential new partners.

Call us on **+49-621-589-2277** to talk to one of our experts. Alternatively, you can email us at welcome@soliqs.com.



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Abbott Laboratories
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