



**QUALISKILLS**  
Pharma Expert Gateway

# QUALISKILLS SILVERLINE LMCS WHITE BOOK

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## INTRODUCTION

### WHO WE ARE

QUALISKILLS is an innovative, integrated and effective business group, providing various high-quality pharmaceutical services for more than 15 years, striving for high standards that meet professional and authorities' requirements.

Our company group provides innovative manufacturing services focusing on last moment product customization by patented packaging technologies, e.g. direct blister/sachet printing solutions, with the related comprehensive services (regulatory, logistics, batch release and such) for pharmaceuticals, medical devices, food supplements, etc. By maximizing the supply chain flexibility and minimizing stock-keeping risks/costs this also enables the effective handling of small quantities, and makes small markets accessible, among other benefits.

We are a dynamic group of experts with many years of experience, gained in the pharmaceutical industry and research institutes.

We have an optimized supply chain model enabling you to enter into small/medium-sized countries that is based on complex regulatory support including pharmacovigilance, packaging optimization, quality control and batch release. Its most advanced element is our innovative primary and secondary packaging technology.

We offer integrated services from bulk import to supply and/or distribution of finished products.

#### QUALISKILLS

We have been working with Bayer, Bluefish, Chemo, GSK, Helm, Humana, Intas Kedrion, Kwizda, Lisapharma, Medinova, Merck, Mylan, Novartis, Pfizer, Ranbaxy, Torrent, Valeant and other valued customers.

We have a solution for managing the special characteristics and difficulties of pharmaceutical production and supply, such as long lead-times, inadequate batch sizes, country specific packaging materials, short shelf-life and high working capital needs.

Our SilverLine technology is the heart of our Last Moment Customization Service that enables us to print blank blisters according to the market requirements with short lead-time, practically for individual customer orders.

### QUALITY POLICY

QUALISKILLS is certified and committed to fully comply with the requirements of EU-GMP through the product life-cycle, QUALISKILLS continuously improve the effectiveness of its quality management system and QUALISKILLS the reliability of its staff, processes and products.

QUALISKILLS aims for exceeding our partners' expectations.



## QUALISKILLS SILVERLINE TECHNOLOGY

### BUSINESS OVERVIEW

Recently, the pharmaceutical industry faced significant changes in business conditions. The growing competition by generic manufacturers and cost cutting measures by the payers cast pressure on the Industry. This requires comprehensive modifications throughout the pharmaceutical value chain. Especially structures and processes of the pharmaceutical supply chain are thereby affected.



For a long time the design of pharmaceutical supply chains was determined primarily by the demand of high delivery reliability and readiness. Pharmaceutical companies have achieved and in many cases still achieve these targets by high inventory levels of finished goods, located close to the customer as well as by extremely reliable production and logistic processes.

Lead-times are long, batch sizes and MoQs are huge, niche products are of low quantities, which force companies to risk high losses in case their sales plans prove to be wrong.

Besides delivery reliability and delivery readiness, cost efficiency, **agility** and **responsiveness** gain more importance in the supply chain objectives. The market players face the following issues on a daily basis:

- How is it possible to translate optimistic or pessimistic forecast into the business reality?
- How to handle the risk of overstock?
- How to handle the risk of stock out?
- How could all these be solved and managed with the existing staff and with the lowest possible investment?

Quite easily, in fact: by taking the entire packaging processes into account and by rethinking all important issues of flexibility.

QUALISKILLS elaborated the answer.

### SILVERLINE AS THE LAST MOMENT CUSTOMIZATION SERVICE

SilverLine is the combination of state-of-the-art and proven technology, customs and quality assurance services, allowing the manufacturers to supply the markets with ease and efficiency, with low investment and risk, enjoying the benefit of our **Last Moment Customization Service (LMCS)**.



The combination of this new technology and our high-quality services help our partners to minimize their stock holding and maximize their flexibility. It helps them also to develop a regional supply strategy in country-specific packaging instead of suffering the hurdles and costs of multilingual packaging approach.

Using SilverLine LMCS, all markets can be served at short notice on demand without dedicating significant stocks for specific countries prior to proven market needs.

## PREREQUISITES

The requirements from customers' point of view along with the advantages and possibilities of the SilverLine LMCS:

## REGULATORY

Our partners have to register us as a Manufacturing Site, and Module 3.2.P.7. of the registration dossier has to be checked and evaluated, if any variation is needed.

Sometimes it might be necessary to revise the blister artwork and to notify the concerned Health Authorities.

We support you in coordinating and performing the submissions of any necessary notifications and/or variations, as well as preparing, checking and approving the artworks before printing.

The entire process should optimally take approximately three months only, but it may vary depending on local rules and authorities.

## LOGISTICS

SilverLine technology enables companies to optimize their stock holding and minimize losses, resulting from improper forecasting, unfavorable market changes and huge batch sizes.

QUALISKILLS has a highly developed supply chain and very flexible production planning which can handle short lead-times for packaging orders, just-in-time deliveries for packaging materials and on-time deliveries to the customers.

By manufacturing the products in semi-finished form and giving the chance to decide on secondary packaging four weeks prior to the requested delivery date, the investment in packaging materials and warehousing can be minimized and the destruction of expiring unsold volumes can be avoided.

QUALISKILLS is able to manage the production in the following ways:

- purchasing bulk product and primary pack it into blank blisters, keep them on stock and apply country specific secondary packaging for small quantities later on  
or



- purchasing blank blisters, keep them on stock and apply market specific secondary packaging for small quantities later on

Final decision on the secondary packaging can be made even in two weeks prior to the production that provides high flexibility in forecasting and also secures that the latest version of packaging materials can be used.

Our logistic and warehousing service partner is UPS Healthcare Hungary Ltd., whose main business line is pharmaceutical warehousing, in modern, well-equipped premises, with 7000-pallet-capacity so we can provide tailor-made services, which meet all expectations.

Benefits at a glance from logistic point of view:

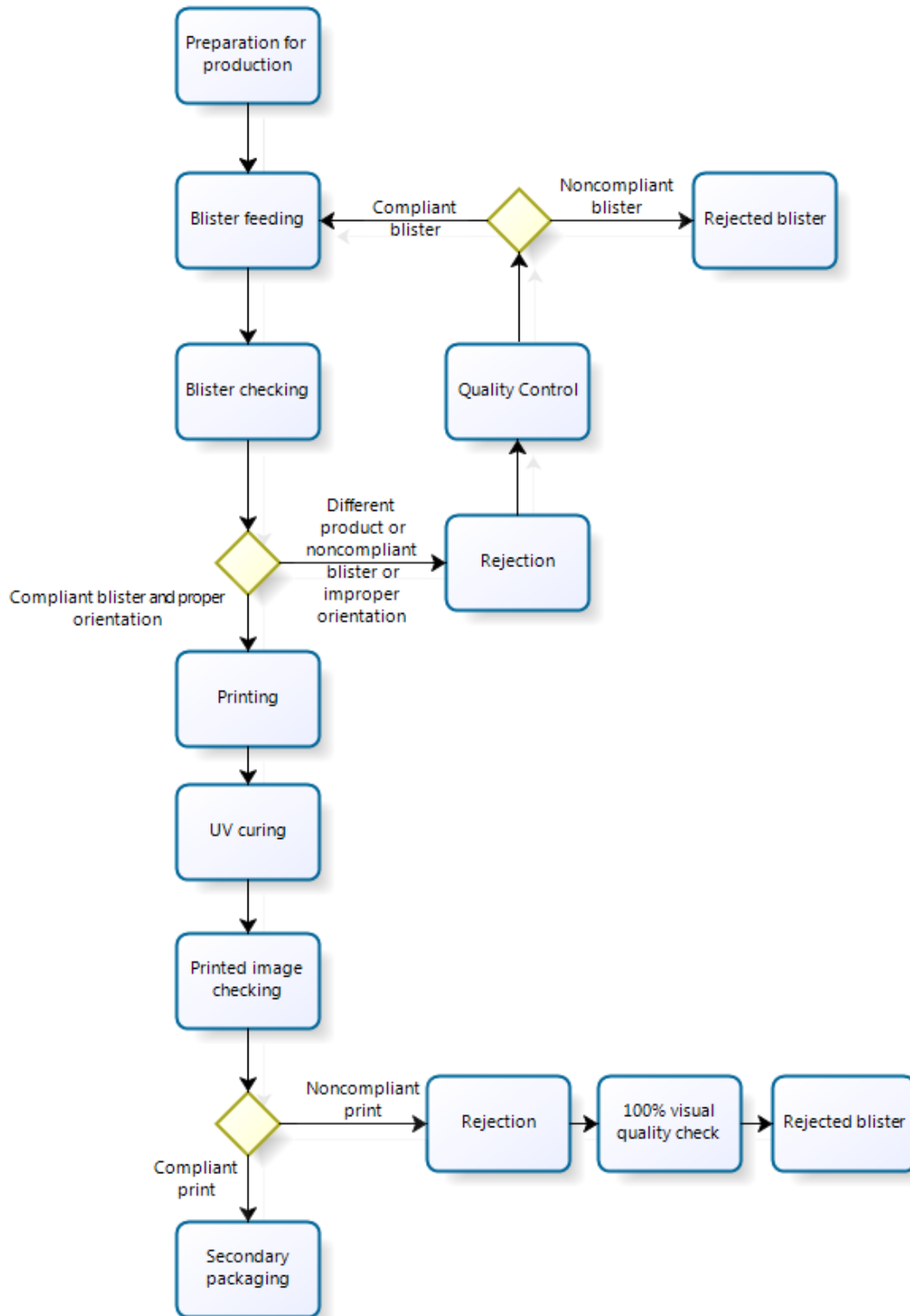
- Reduction in package cost for small order volumes
- Reduction of inventory investment
- Reduction in inventory storage area
- Fast change over
- Multiple feeding stations allow format change on the fly
- Lower administration cost
- Eliminates write-off cost for discontinued inventory
- Quick response lowers lead times
- Prevents potential lost opportunities by meeting market demand
- No extra charge below the minimum order quantity

Your blank blister product should meet the following specifications:

- Size: 28-110 mm width, 50-200 mm length and 5-35 mm high
- Tight packed in carton paper collection box with same direction, at least 10 blisters per unit
- Paper collection box, well packed in shipping box on pallets, covered with stretch foil
- Each magazine/ paper collection box marked with batch number, product name, strength and expiry date
- Shipping box need to be labeled and marked with product name, strength, expiry date, batch number, and quantity.
- Alu- foil specification:
  - minimum 50 % of the printing lacquer coating shelf life, but not less than 6 months
  - free from oily and fatty spots (should not touched without protection gloves)
  - Welded pattern should smooth, clean and homogenous surface within one lot/batch
- Blister need to be flat and also need to be free from external impact/influences, what can occur curving and wrapping of the blister shape
- Blank blister should contain embossed or printed data (batch number, expiry date)



### SILVERLINE LMCS PRODUCTION PROCESS FLOW





We have a couple of built-in blister checking algorithms enabling safe and mix-up free production.

Product identification checking:

- ✓ UV invisible pre-printed GS1 Data Matrix ECC200
- ✓ Visible pre-printed GS1 Data Matrix ECC200

Blister orientation checking:

- ✓ Embossed data (e.g. BN, EXP)
- ✓ Visible pre-printed GS1 Data Matrix ECC200
- ✓ UV invisible pre-printed GS1 Data Matrix ECC200
- ✓ UV marker sign (e.g. arrow, mark, spot, etc.)

Printed blister image checking:

- ✓ Master Image reference based
- ✓ Using unique method distinguishing the different artwork elements (images and characters), their sizes and pixel count

## SMART TECHNOLOGY FOR MAXIMUM FLEXIBILITY AND EFFICIENCY

SilveLine LMCS provides cost effective safety, reliability and flexibility.

### TECHNOLOGY

- Reliable and state-of-the-art technology
- Reliable and straightforward equipment
- Reliable, efficient and flexible operating procedure
- Significantly simplified changeover

### MARKING

- Content of marking: optional text, graphics, barcode

### 360 DPI & 72 MM WIDTH PRINTOUT

- The 360 dpi human readable printout resists mechanical stress, acids, solvents and other chemicals
- 360 x720 dpi resolution
- Monochrome black print





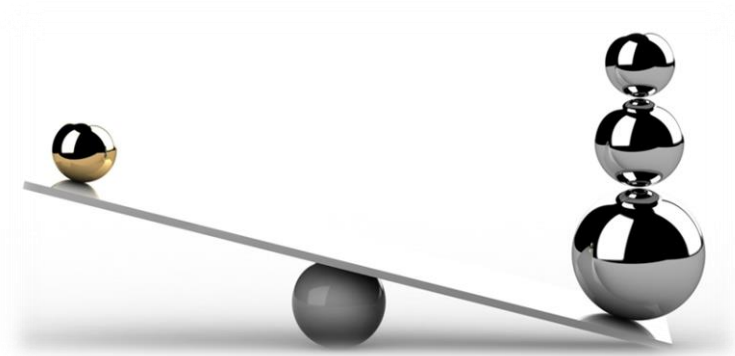
## REGULATIONS AND CERTIFICATIONS

- GAMP 5
- cGMP
- CE

## CONVENTIONAL SUPPLY CHAIN VS. SILVERLINE LMCS

We prepared a simple comparison to show the clear advantages of our solution

<b>Conventional Supply Chain</b>	<b>SILVERLINE LMCS</b>
<p><b>Supplier delivers finished products, according to batch sizes</b></p> <p><b>The company is not able to react fast for the monthly changes of the markets</b></p> <p><b>It is difficult to manage new launches</b> <b>the capital is blocked in country specific finished product</b></p>	<p><b>Partner delivers bulk/blister to QUALISKILLS (either from the EU or non- EU production site)</b></p> <p><b>Stock at QUALISKILLS remains in the property of Partner, until it is not packed and taken over by third party</b></p> <p><b>QUALISKILLS arranges monthly production and delivery to third party (including batch release as well)</b></p>







## SUMMARY

By using our technology, one can maximize its supply chain flexibility, and minimize the risks and costs of being inflexible. There is no need for stocking country-specific primary packaging materials, or calculate with extra financing, destruction and write-off costs for stocks. Production from one mother batch also means lower analysis and release cost.

We can handle bulk/blister deliveries from EU/non-EU countries and present the most optimal production and supply plan, based on market specific requirements.

Based on the 15+ years of experience in the pharmaceutical industry, we understand the challenges arisen in the last few years in the European Union. 28 countries with 28 independent markets, in a rapidly changing environment with decreasing and more controlled healthcare and pharma budgets – different pricing and reimbursement systems with strict and not fully harmonized regulatory regimes - in an environment, where the financial resources are becoming limited in the pharma supply chain. The short product lifecycle, on demand delivery requirements with 4-6- months manufacturing lead time of inadequate batch sizes, in addition to country specific packaging material and higher capital needs are shrieking for a solution to avoid stock-out or overstocking.

Our answer to these challenges is an innovative, effective and integrated business group, providing high- quality services to the players in the pharmaceutical industry. With a wide range of flexible service portfolio for specific needs, harmonized manufacturing and QA services covering all elements of the supply chain from bulk import to finished product supply - we offer the value chain elements of Regulatory, Production and Supply chain management.

Our aim is to minimize your stock holding and maximize its flexibility by last moment customization at the time of dispatch. With production optimization and regulatory harmonization, big or small markets can be served without dedicating significant stocks prior to real market demand.

Our SilverLine packaging concept for non- printed blister foils, with reduced change over time, immediate reaction to customer orders, short manufacturing lead times, along with strategic partnerships with key suppliers enable our partners to avoid product destruction, and to reject low volume markets or order inadequate volumes. Low analytical and batch release cost, no stockpiles of country specific packaging material are advantages that no one should ignore.

There is no stop for us to develop our SilverLine to a more sophisticated level. We are already working on the development of the second generation – SilverLine APD – using even more advanced technology for the next generation machinery.

