

NEWSLETTER

Spring '24 Edition

IN THIS EDITION



Message from Customer Services Director

Thank you again to those of you that took the time to respond to our request for feedback via the annual customer satisfaction survey. We are pleased to report that we have maintained average scores of 4+ out of 5 across the board. There are certain customer-specific suggestions for opportunities for us to improve in the future and these will be reviewed and implemented where possible. We therefore may be in touch with you in the coming months to discuss ways of working and any improvement plans to be considered to ensure we can work in line with our business key values of working in partnership and delivering excellence where possible.

We are working on improving and changing our approach to gathering feedback from our customers this year, but if you didn't get the chance to complete the survey and would like to, then please reach out to (vhart@Laleham.com).

A handwritten signature in black ink that reads "Vicky Hart". The signature is fluid and cursive.

Vicky Hart, Customer Services Director

HAPPY ANNIVERSARY TO US!

2024 is a celebration year for us here at
Laleham.

The first of our celebrations was the 10th
Anniversary of the Kirkham site, UPL as it was
known, becoming part of the Laleham family on
6th February 2014!

We continue to invest in the future of the site.
A warehouse expansion, various line upgrades,
vessel upgrades, a new licensed medicine
vessel, +£2m in progress Project Shield
licensed medicine upgrade, plus many people,
infrastructure and organisational investments.
The foundations are firmly in place for us to
continue to grow together!



We have another two anniversaries coming in 2024.
Let the celebrations begin!!!

ACCREDITATIONS & CERTIFICATIONS



MHRA RE-INSPECTION

Anyone operating in the Licensed Medicine category will understand what it takes to maintain exceptionally high standards. We are delighted that Laleham Health and Beauty (Kirkham site) recently completed our routine MHRA re-inspection in Jan 2024 in accordance with Article 40 of Directive 2001/83/EC; The Human Medicine Regulations 2012 (SI 2012/1916), and will continue to be certificated GMP compliant for a further 3 years. The Alton site was previously inspected in March 2022 with a similar successful outcome, with a validity period of 3 years.

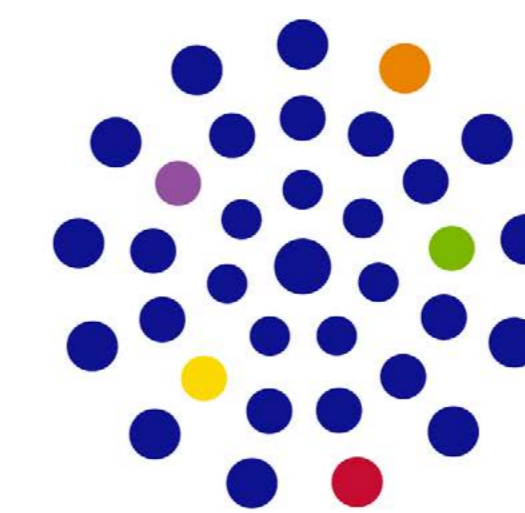
We offer non-sterile, semi-solid and liquid medicinal & medical device product manufacture from both the Kirkham and Alton sites, with diverse technologies and packaging formats available – aluminium and plastic tubes, jars and tubs, bottles of all shapes and sizes, and have a combination of flexible or high automated production lines to meet most product needs. Our onboarding teams continue to gain expertise in product transfer which this complex arena requires. So, please do let us know if we can support your product needs.

Not only are we delighted to achieve this recognition of our continued investment in this category, but also the additional Mutual Recognition Agreements (MRA) in place provides the coverage of FDA requirement for OTC drug products. We are very proud that not only we are MoCHRA registered with FDA for cosmetics (more on the next page) but continue to be FDA registered for OTC drug products supplied to USA.

Our Beauty and Nutritional customers continue to benefit from such high standards of GMP and integrity.

That's what we think helps to make us **THE trusted manufacturing partner in Health and Beauty.**

Thanks for trusting in us!



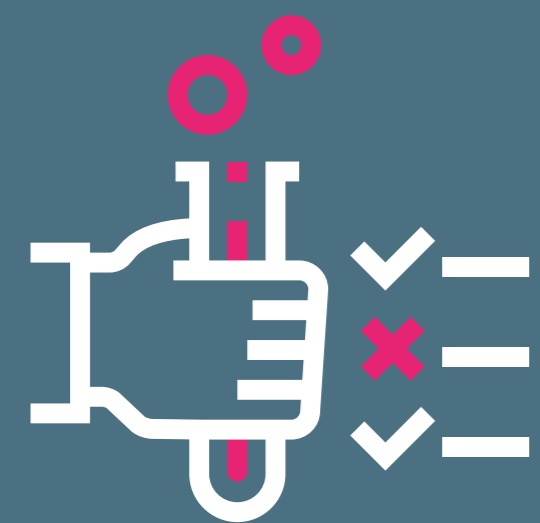
MHRA
Regulating Medicines and Medical Devices

Sedex | Member

CORPORATE SOCIAL RESPONSIBILITY

Both Laleham Alton and Laleham Kirkham sites have both had their 4 **Pillar SMETA Audits completed on each site** in January and February, Over the 2 day audits on each site there was only 1 observation recorded between both audits which is our best audit result to date. Laleham continues to develop and improve its CSR credentials in partnership with our parent company DCC and with our CSR partners SGS, SEDEX & EcoVadis.

REGULATORY UPDATE



Modernization of Cosmetics Regulation Act (MoCRA)

If you were not already aware, we're happy to confirm that we have successfully **completed FDA Cosmetic Facility Registration for all three of our sites.**

If you're selling products into the US, your Responsible Person will require our FEI registration number (FDA Establishment Identifier) to list products on the FDA Cosmetics Direct portal. If you haven't yet received our details, please get in touch with our Regulatory Team.

TEA TREE OIL

The Committee for Risk Assessment (RAC) has published the opinion regards Tea Tree Oil (also known as Melaleuca Oil) confirming its classification as a CMR 1B under EU Classification, Labelling and Packaging (CLP) Regulation. Substances classed as CMRs are prohibited for use in cosmetic products, unless industry applies for exemption. Suppliers can now submit safety data on this oil to try to defend its use, but there is a chance that Tea Tree Oil may be banned in the EU and NI.

Our Cosmetics Regulatory Team is closely monitoring this situation and is conducting an internal review to identify products that may be impacted, and we will advise your regulatory contacts accordingly.

EU REACH RESTRICTION ON MICROPLASTICS

EU has adopted a broad interpretation of microplastics to include all synthetic polymer particles (SPMs) less than five millimetres in diameter that are organic, insoluble and resistant to degradation. The restriction applies to microplastics on their own and in certain consumer products, such as cosmetics. The amendment to the EU REACH Regulation entered into force on 17 October 2023 and will take effect on a phased basis from between 2023 and 2035. The transition periods that apply to cosmetic products are as follow:

17 October 2023 - microplastics on their own and when intentionally added (i.e. exfoliating microbeads, plastic loose glitter)

17 October 2027 - microplastics for use in rinse-off cosmetic products

17 October 2029 - microplastics for use in the encapsulation of fragrance and use in leave-on cosmetic products

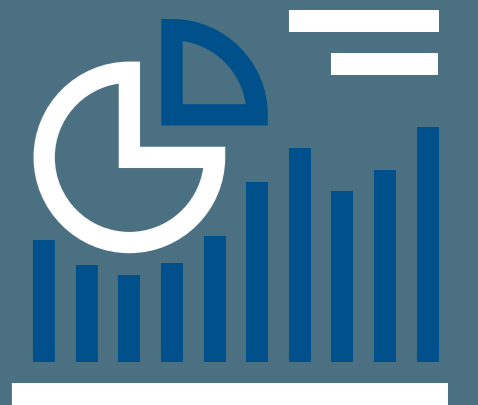
17 October 2035 - microplastics for use in lip products, nail products and make-up

On 14 February 2024, Cosmetics Europe and the European Federation of Cosmetics Ingredients (EFFCI) published joint guidance on EU restrictions on microplastics under REACH. Our Cosmetics Regulatory Team is in the process of reviewing the guidance and contacting suppliers to identify raw materials that are in scope of this new regulation to be able to assess any potential impact.

As for the UK REACH, microplastics restriction will not be implemented automatically.

SITE INVESTMENTS - PROJECT SHIELD

Kirkham Site Development plans are developing on track.



Project Shield

Protecting our colleagues, our contractors & our products

We have already opened a new manufacturing room for our pilot batches and our new pharmaceutical dispensary. This will **double the dispensary capability** at site and will **segregate pharmaceutical products** from cosmetic, nutritional, and medical device.

As part of the site development over the next 12 months we are also creating the following areas: a new hygiene facility, a new raw materials warm room, a new cosmetic dispensary and a new changeover area.

We will continue to keep you up to date on this exciting development.



MEET OUR OPERATIONS DIRECTORS



Mariola Balczerowska,
Alton Operations Director,
November 2023

Prior to joining Laleham, I spent 10 years of my career working at one of the largest dairy companies globally and held various roles in operations and projects. I have led numerous operational functions including Production and Technology Development, Engineering, Quality, Environment and Health & Safety, Logistics, and Planning, among others.

My strengths lie in driving positive step-change performance, effectively managing incremental change, fostering team collaboration and driving engagement within the organization.



Jack Thompson,
New Operations Director at Kirkham,
January 2024

I've been at the Kirkham site for over 3 years and joined as Operations Manager. The recent change in my role means I now have overall control of factory operations including engineering and facilities teams. Before joining Laleham I've held positions within a highly automated packaging site and in high-risk food factories, always working within Operations.

I am passionate about developing people, Health & Safety and ensuring the customer receives a high-quality product, when they want it. If you would like any more information on site development plans or about product services, please do get in touch.

SUPPLY CHAIN DISRUPTION

We are continuing to monitor the situation in the Red Sea and are working with our suppliers to minimise disruption to our supply chains. Whilst we experienced some initial delays on a small number of deliveries with containers being rerouted, lead times have now been adjusted accordingly to reflect this. We are in regular communication with our suppliers and logistic providers to help ensure deliveries remain to schedule.

If you would like to feedback on the newsletter content, please contact Vicky Hart on vhart@laleham.com or your Account Manager.

For the latest updates from Laleham Health & Beauty, please refer to our website www.laleham.com and join us on LinkedIn.

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