Galenisys Business Cases

This is how we help companies

Case Study – Verifying GMP Compliance in a Complex Asian API Supply Chain

Context

In the mid-2000s, European regulatory expectations evolved significantly, raising the bar for Active Pharmaceutical Ingredient ("API") traceability and GMP compliance.
New EMA requirements made it clear that **Marketing Authorisation Holders ("MAHs")** had to demonstrate that active substances were manufactured **in full compliance with GMP**, including **on-site audits of the actual manufacturing facilities** and not only of European suppliers or distributors.

This was not surprising since for over 20 years Galenisys have often found serious non compliances when auditing API manufacturers outside the EU.

In this case, a European pharmaceutical company sourcing **Histamine Dihydrochloride** from Asia was facing increasing regulatory pressure to confirm its supply chain compliance.
Given Galenisys' long-standing presence in Asia, and our hands-on experience in GMP auditing, regulatory due diligence, and supplier qualification, we were asked to investigate the situation directly **on the ground**.

The Challenge

At first sight, the documentation provided appeared reassuring:

- A named Chinese "supplier" based in **Hangzhou**
- A completed raw material questionnaires
- A GMP certificate issued by Chinese authorities

However, as the review progressed, a number of serious inconsistencies emerged:

- Manufacturing was later claimed to take place in **Suzhou**, not Hangzhou
- QA roles and responsibilities were unclear and did not align with GMP expectations
- GMP documentation showed signs of alteration and possible falsification

Company registered at :
28, rue Meslay
75003 Paris, France
Tel: +33 1 45 55 44 14
Contact: info@galenisys-pc.com

Offices at
11, Rue Notre Dame de Nazareth
75003 Paris, France
Tel : +33 6 32 32 99 27
E-mail : steve.biddulph@galenisys-pc.com

- **In particular, neither party was willing to host an on-site audit or plant visit.**

The risk for the MAH was evident: continuing to source the API without certainty on GMP-compliant manufacturing would expose the company to major regulatory findings, potential supply disruption, and reputational damage.

Galenisys Intervention

Working directly in China, Galenisys conducted a **thorough and pragmatic due-diligence investigation**, combining regulatory expertise with deep local operational knowledge.

Our work included:

- Detailed cross-checking of raw material questionnaires, certificates, and declared manufacturing sites
- Verification of QA roles and responsibilities against applicable GMP standards
- Critical assessment of GMP certificates for authenticity, scope, and format
- Direct discussions with the various stakeholders involved across the supply chain

Through persistent follow-up and expert scrutiny, Galenisys established that:

- The apparent “supplier” was in reality a **trading company**, not a manufacturer
- The GMP certificate had been **manipulated** to include Histamine Dihydrochloride
- The certificate was a **copy**, not an original (incorrect background, missing SFDA security markers)
- At that time, no **credibly GMP-certified manufacturer of pharmaceutical-grade Histamine** could be confirmed in China.

Outcome & Value Delivered

As a result of our intervention, Galenisys provided the client with:

- A clear and documented **risk assessment aligned with EMA expectations**
- Protection against the use of **non-GMP-compliant APIs**

Company registered at :
28, rue Meslay
75003 Paris, France
Tel: +33 1 45 55 44 14
Contact: info@galenisys-pc.com

Offices at
11, Rue Notre Dame de Nazareth
75003 Paris, France
Tel : +33 6 32 32 99 27
E-mail : steve.biddulph@galenisys-pc.com

- Avoidance of regulatory exposure, inspection observations, and potential recalls

Most importantly, the client avoided building its regulatory dossier on an apparent "paper only" GMP compliance basis, unsupported by operational reality.

Why This Matters to Our Clients

This case highlights a fundamental principle:
documentation alone does not guarantee compliance, particularly within complex international supply chains. You can imagine the cost & delay impact if – for example – this type of situation is exposed during a Pre-Approval Inspection!

Galenisys brings to its clients:

- **On-site, in-territory expertise**
- A deep understanding of **regional regulatory realities**
- The ability to identify **early warning signs of non-compliance**

We don't just review documents, **we verify the facts on the ground**.

Company registered at :
28, rue Meslay
75003 Paris, France
Tel: +33 1 45 55 44 14
Contact: info@galenisys-pc.com

Offices at
11, Rue Notre Dame de Nazareth
75003 Paris, France
Tel : +33 6 32 32 99 27
E-mail : steve.biddulph@galenisys-pc.com