Press Release

DUE DILIGENCE

Atessia
Life Science Advisors

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Atessia Conducts Regulatory Due Diligence for BC Partners in the Acquisition of Biogaran

In late July 2025, Atessia, a consulting firm specialized in regulatory and pharmaceutical affairs, supported BC Partners in the acquisition of Biogaran, a leading player in the French generics market, by conducting an in-depth regulatory due diligence.

This assignment, central to the strategic stakes of the transaction, provided the fund with a clear, documented, and actionable view of the risks and opportunities associated with the product portfolio, quality systems, and compliance obligations.

In pharmaceutical mergers and acquisitions, assessing the value of an asset cannot be limited to financial indicators: it depends on the robustness of regulatory dossiers and the compliance of pharmaceutical systems. Marketing Authorisations, the history of variations, the integrity of the PSMF, the traceability of clinical data, the resilience of the supply chain, and GxP compliance are all decisive parameters in evaluating the strength and sustainability of a portfolio. The purpose of regulatory due diligence is to scrutinize these elements in order to detect critical issues, anticipate compliance risks, and identify opportunities for optimisation.

In the context of BC Partners' acquisition of Biogaran, Atessia leveraged its expertise to conduct a comprehensive regulatory due diligence. The review of dossiers and processes provided a detailed and actionable understanding of the key issues, enabling investors to rely on a well-founded decision and ensuring a smooth regulatory integration from the earliest post-acquisition stages.

> *Our role is to transform regulatory complexity into a strategic advantage. By providing a clear and actionable view of MA, pharmacovigilance, quality, and supply issues, we help investors secure their decisions while preparing for regulatory integration. This case illustrates Atessia's ability to act on high-profile transactions, with the scientific and operational rigor expected by the market."*
>
> — ***Géraldine Baudot-Visser**, CEO & Founder, Atessia*

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Added Value Through Atessia's Regulatory Due Diligence

- **Securing the investment decision through a risk mapping directly usable by decision-makers.**

- **Strategic alignment between business ambitions and regulatory requirements, to accelerate value creation post-acquisition.**

The findings of a due diligence are not limited to providing a snapshot: they directly inform negotiations. The prioritisation of risks – critical, major, or minor – provides a solid basis for adjusting valuation, defining conditions precedent, or planning corrective measures. In this way, Atessia delivers its clients a decisive advantage in strategic discussions.

Atessia's Regulatory Due Diligence Scope

As part of due diligence assignments, Atessia provides investors and pharmaceutical companies with comprehensive technical and regulatory expertise covering the entire lifecycle of health products. Our analyses may include, among others:

- **Marketing Authorisations (MA): dossier integrity, regulatory status, variations (Type IA/IB/II), renewals, extensions, alignment of SmPC/leaflet/labelling.**
- **Product lifecycle & strategy: site, raw material, or process changes, bioequivalence, portfolio management, and obsolescence.**
- **Pharmacovigilance & post-marketing: PSMF compliance, case reporting, CAPA, signal detection, PSUR/PBRER, and post-authorisation commitments.**
- **Quality & GxP compliance: GMP status of referenced sites (EudraGMDP), inspection history (ANSM/EMA), QMS (deviations, OOS/OOT, complaints, recalls), Quality/Technical Agreements.**
- **Supply chain & serialisation: compliance with FMD (Directive 2011/62/EU), anti-counterfeit controls, supply continuity, and shortage management systems.**
- **Operational regulatory affairs: robustness of submission/maintenance processes, timelines, document control, traceability of commitments, and interactions with authorities (ANSM/EMA).**

To facilitate prioritisation, findings are categorised within a Critical/Major/Minor matrix, with associated recommendations: immediate measures, mitigation plans, and regulatory integration roadmap.

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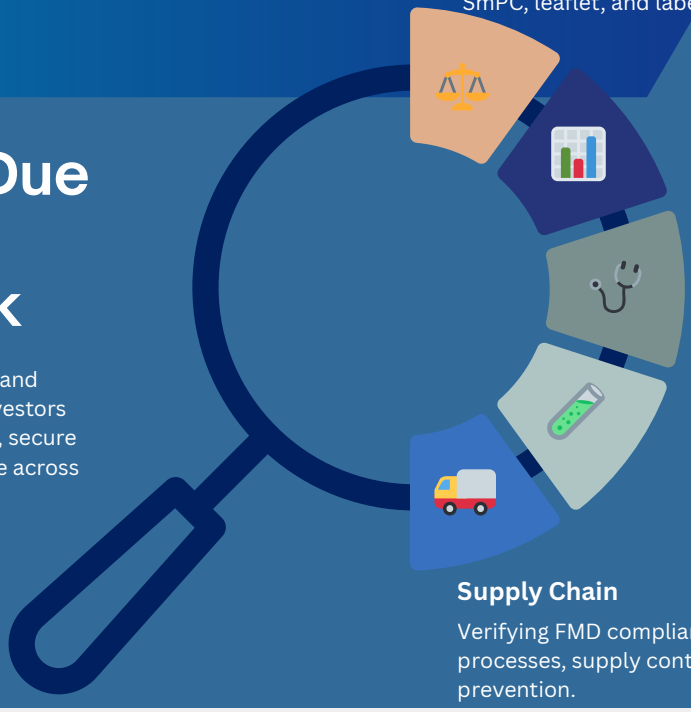
Atessia's Due Diligence Framework

A comprehensive regulatory and technical review ensuring investors and companies identify risks, secure compliance, and unlock value across the product lifecycle.



Regulatory Affairs
Assessing the integrity of Marketing Authorisation dossiers, regulatory status, variations, renewals, and alignment of SmPC, leaflet, and labelling.

Product Strategy
Reviewing lifecycle management, site or process changes, raw materials, bioequivalence, portfolio optimisation, and obsolescence risks.

Pharmacovigilance
Evaluating PSMF compliance, case reporting, signal detection, CAPA, PSUR/PBRER, and post-authorisation commitments.

Quality & GxP
Auditing GMP/GDP compliance, inspection history (ANSM/EMA), QMS robustness (deviations, recalls, OOS/OOT), and quality agreements.

Supply Chain
Verifying FMD compliance and serialisation processes, supply continuity, shortage prevention.

Post-Acquisition Support

An effective due diligence does not end with the delivery of a report: it prepares the future. By supporting the implementation of a regulatory roadmap, Atessia facilitates the integration of quality, pharmacovigilance, and regulatory affairs systems, ensuring operational continuity and turning the acquisition into a long-term success.

This approach now finds its natural extension with **Aphilæ Pharma**, the **NEW Exploitant** entity within the Atessia & Co. group, which enables us to directly assume local pharmaceutical responsibilities related to making medicines available on the French market.

Pharmacovigilance, batch follow-up, medical information, promotional compliance, management of early access programs, and supply continuity: Aphilæ takes charge of the missions that fall under the pharmaceutical responsibility and guarantee patient safety. By combining Atessia's strategic vision with Aphilæ's operational capability, we offer investors and pharmaceutical companies an integrated solution that is rare on the market: from risk assessment upstream to compliant and sustainable exploitation downstream.

Aphilæ Pharma
Ahead French Exploitant

About Atessia & Co.

Atessia is an independent consulting firm in regulatory affairs, pharmaceutical affairs, and strategy for the life sciences industry. Based in Paris, the team supports laboratories, biotechs, and investors across the entire product lifecycle: pre-MA, MA, post-MA, pharmacovigilance, quality/GxP, M&A transactions, and post-deal integrations. Our differentiator: deep expertise combined with operational deliverables directly usable by investment committees and executive boards.

Atessia & Co. today brings together several complementary entities:

- **Atessia** (regulatory and strategic consulting),
- **Amarylys** (provision of specialized talent for the life sciences industry),
- **Atessia Vigilances** (specialized service provider in the management of health product vigilances),
- **Aphilæ Pharma (**pharmaceutical establishment holding French Exploitant status, approved by ANSM, assuming local pharmaceutical responsibility).

This integrated model provides stakeholders across the healthcare sector — laboratories, biotechs, investors, and international partners — with a unique solution on the French market, combining strategic vision, operational execution, and direct pharmaceutical responsibility.

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