

LIFE SCIENCE SERVICES

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Licensing Agreements Financial Management: A Blueprint for Success

Leveraging the use of modern ERPs for effective management of milestones and obligations.

In the life sciences industry, licensing agreements are essential financing methods.

Managing complex license agreements is crucial to ensuring compliance, timely delivery, and financial transparency. License agreements encompass a broad spectrum of obligations, from product development and regulatory approvals to milestone payments and royalties.

These agreements outline the framework for collaboration and clearly define each party's commitments, such as regulatory filings, supply responsibilities, and financial obligations tied to clinical milestones and sales achievements.

Tracking these multifaceted requirements manually is time-consuming and prone to errors that lead to costly delays and compliance risks.

Modern ERP solutions, provide an integrated, user-friendly solution designed for small to mid-sized enterprises, particularly suited for the dynamic needs of biotech and biopharma companies engaged in multi-faceted collaborations.

Through its project management, financial, and purchasing modules, SAP ERP enables users to track the progress of milestones, manage contractual payments, and ensure compliance with regulatory requirements—all within a single platform.

SAP's in-memory database capabilities enhance this functionality by providing real-time insights and analytics, enabling decision-makers to monitor project costs, revenue recognition, and critical delivery timelines with high precision.

SAP ERP facilitates the centralisation and automation of key elements in license agreements. Milestones and Royalty obligations follow up become a seamless tasks. The Project Management module serves as the core repository for all project-related costs and revenues, allowing stakeholders to link sales and purchase orders directly to specific project codes for a comprehensive view of financial commitments.

The Project Management module simplifies revenue recognition and royalty tracking, ensuring that all payments and obligations align with both IFRS and US GAAP standards. Additionally, SAP ERP's flexible reporting capabilities enable users to generate tailored reports. Reporting on milestone achievements, regulatory expenses, and overall project status, becomes routine and requires no time to produce.

By automating routine processes and providing a centralised platform for real-time tracking, SAP ERP empowers companies to efficiently manage contractual obligations, optimise collaboration, and make data-driven decisions that drive long-term value.

Introduction to the Business Case

This business case examines the implementation of SAP ERP in managing license agreements within the life sciences sector. We focus on a specific license agreement involving the Licensor and the Licensee for the development and commercialisation of a monoclonal antibody targeting a protein receptor found on activated T cells in the immune system.

This case demonstrates how leveraging advanced ERP systems can significantly enhance the efficiency and compliance of managing complex licensing agreements in the pharmaceutical industry.

The license agreement in question involves substantial financial commitments, intricate milestone payments, and various regulatory obligations. By utilising SAP ERP's Project Management capabilities, we aim to showcase how life science companies can streamline the tracking of milestones, financial transactions, and regulatory compliance associated with such agreements.

Our analysis detail how SAP ERP is employed to:

- Create a comprehensive project structure for the license agreement
- Track and manage payment obligations and revenue recognition in accordance with IFRS and US GAAP standards
- Monitor and ensure compliance with regulatory requirements and audit obligations
- Provide real-time visibility into the financial and operational aspects of the agreement

This case study demonstrates how integrating these advanced ERP solutions transform the management of license agreements, improves financial control, enhance compliance, and enables more informed decision-making capabilities in the dynamic landscape of life sciences.

“Outdated financial processes create operational bottlenecks and put at risk the ability to scale successfully.”



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Payment Obligations and Revenue Recognition (Licensee)

Payment Type	Amount	Timing	IFRS Recognition	US GAAP Recognition
Upfront Payment	€20,800,000	Upon signing	IFRS 15 (Para 31-38): Recognise over time as performance obligations are satisfied	ASC 606 (Step 5): Recognise when control is transferred to the customer
Development Milestone	Up to €15,000,000	Upon achievement	IFRS 15 (Para 56-58): Recognise when highly probable that significant reversal will not occur	ASC 606-10-32-11 to 32-13: Recognise when constraint is resolved
Regulatory Milestone	Up to €67,500,000	Upon achievement	IFRS 15 (Para 56-58): Recognise when highly probable that significant reversal will not occur	ASC 606-10-32-11 to 32-13: Recognise when constraint is resolved
Sales Milestone	Up to €150,000,000	Upon achievement	IFRS 15 (Para 56-58): Recognise when highly probable that significant reversal will not occur	ASC 606-10-32-11 to 32-13: Recognise when constraint is resolved
Royalties	Tiered percentages	As earned	IFRS 15 (Para B63-B63B): Recognise as sales occur	ASC 606-10-55-65: Recognise as sales occur

Licensor Obligations and Audit Requirements

Obligation/Step	Timing/Frequency	Regulatory Requirement
Manufacturing and Supply	As per agreement schedule	GMP compliance
Technology Transfer	Within specified timeframe	Adherence to tech transfer protocols
Regulatory Filings	As needed for development	Compliance with FDA/EMA requirements
Support	Ongoing	Adherence to safety reporting regulations
Pharmacovigilance	Ongoing	Adherence to safety reporting regulations
Internal Audits	Annually	SOX compliance (if applicable)
External Audits	As specified in agreement	Financial statement audit requirements
Royalty Reporting	Quarterly	Accurate financial reporting

“Don’t let financial inefficiencies hold your licensing agreements back. Discover the path to financial excellence today.”

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SAP ERP Implementation Use Case

To effectively manage this license agreement using SAP ERP, we utilise the following modules and transactions:

- Project Management Module: Create a main project "Licensing" with sub-projects for each major phase (e.g., Development, Regulatory, Commercialisation).
- Financial Accounting Module: Set up specific accounts for milestone payments, royalties, and related expenses. Use journal entries to record payments received and revenue recognised.
- Sales Module: Create a customer account for the Licensee to track all transactions related to the agreement such as sales orders.
- Purchasing Module: Manage expenses related to manufacturing and technology transfer, creating purchase orders and contracts.
- Inventory Module: Track the manufacturing and supply of the product. It can track inventory in-house and stored in 3rd parties, without the need for the 3rd party to access the ERP.
- Production Module: Manage the production process including GMP compliance (optional).
- Document Management: Store and manage all related documents, including the license agreement, regulatory filings, and audit reports.

Step	Module	Action	Purpose
1	Project Management	Create main project and sub-projects	Establish project structure for license agreement, track milestone payments, royalties, and expenses.
2	Financial Accounting	Set up specific accounts	Record of transactions.
3	Sales	Create customer accounts	Centralise all agreement-related transactions including sales orders.
4	Purchasing	Set up vendors and expense categories	Manage manufacturing and tech transfer expenses
5	Inventory	Create item master data	Track manufacturing and supply, internally and externally.
6	Production	Set up production orders	Manage production process, internally and externally.
7	Document Management	Upload and categorise documents	Store agreement, regulatory filings, and audit reports



“Modern ERP systems elevate your financial management strategy, ensure regulatory compliance, and build trust with investors.”

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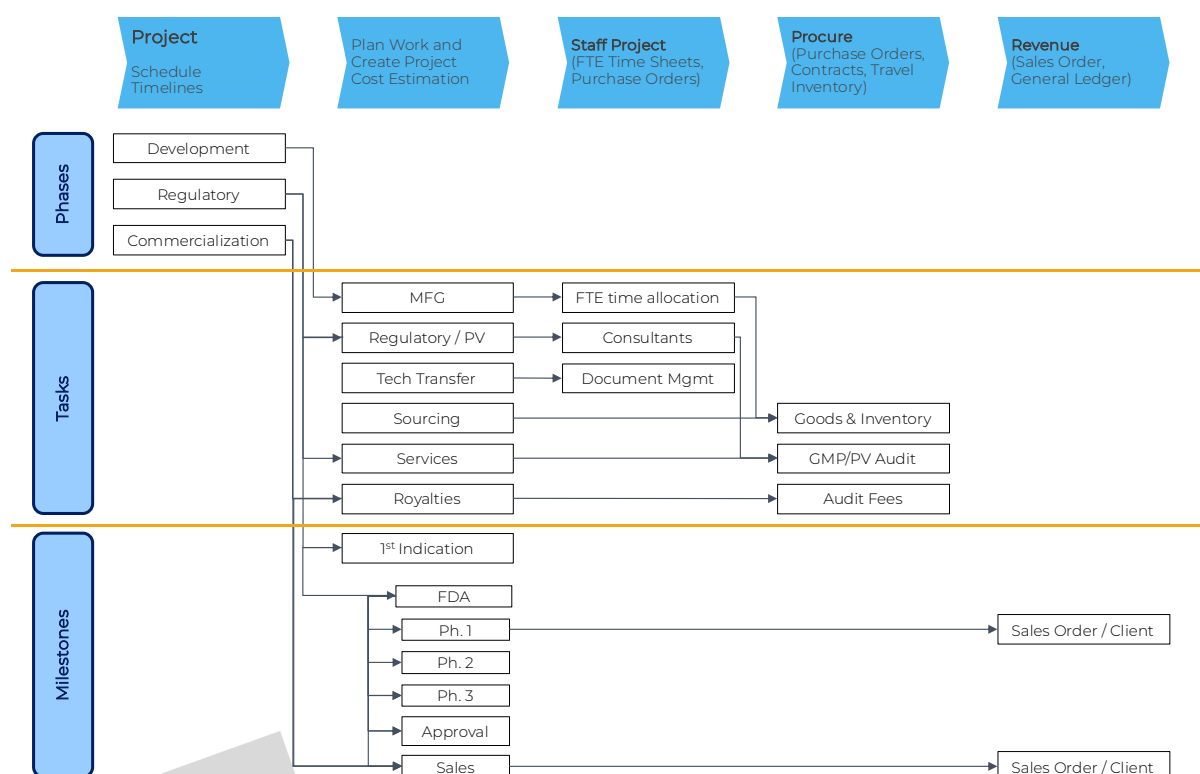
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Key transactions and processes:

- Create project milestones in the Project Management module for each payment and regulatory event.
- Use sales orders to record milestone achievements and trigger invoicing.
- Implement a custom query in SAP ERP to calculate and report royalties based on sales data.
- Set up automated alerts for upcoming milestones, regulatory deadlines, and audit dates.
- Utilise the reporting features to generate real-time financial dashboards, statements and compliance reports.

This implementation provides a comprehensive system for managing the entire lifecycle of the license agreement, ensuring financial accuracy, regulatory compliance, and operational efficiency. Any element can be added and edited anytime during the course of the project. Projects can be saved as templates for future use and can be exported in other formats (Excel, MS Project, etc.).



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Accounting Treatment

The transaction as it happened so far is the following:

- The agreement was signed on 15 December 2023, with an upfront payment of €20,800,000 for four future deliveries (one per quarter) of EUR 5,200,000 each.
- Every delivery costs the licensor 2 million to produce.
- The licensee can reject because of quality any of the batches delivered within 30 days of receipt, assuming the delivery takes 20 days (shipment on 10th, arrival on 30th, so The licensee can reject until the 30th of the following month).
- The first delivery happened on January 3, 2024. The licensee accepted the delivery.
- The second delivery April 1, 2024 was rejected by the licensee.
- The resolution is in arbitrage with an independent quality audit company paid by the licensor.
- What is now the accounting as per IFRS 15 (Paragraphs 31-38) and ASC 606 (Step 5)? When to recognise the costs?
- The 3rd delivery is on hold until the quality issue is resolved. How does it affect the overall revenue recognition?

Based on the events described, here's the accounting treatment under IFRS 15 and ASC 606. Accounting treatment is defined at the sales order level and can be adjusted accordingly and on a need-by basis.

- Agreement Signing (15 December 2023): No revenue recognition at this point. Record the €20,800,000 as a contract liability (deferred revenue).
- Sales Order 1 - First Delivery (3 January 2024):
 - Marking the Sales Order as "Fully Delivered" will trigger the following entries:
 - Recognise revenue of €5,200,000 as the performance obligation is satisfied.
 - Recognise cost of €2,000,000.
 - Reduce contract liability by €5,200,000.
- Sales Order 2 - Second Delivery (1 April 2024):
 - Marking the Sales Order as "Partially Delivered" will trigger the following entries:
 - No recognition or revenue yet.
 - Recognise cost of €2,000,000 as an expense.
 - Contract liability remains unchanged for this delivery.
- Purchase Order - Arbitrage Process:
 - Costs associated with arbitrage are expensed as incurred in the project.
- Sales Order 3 - Third Delivery (On Hold):
 - The Sales Order is open.
 - No revenue recognition or cost recognition until the quality issue is resolved and delivery occurs.



"Modern ERP solutions are no longer optional—they are the cornerstone of financial excellence in life sciences."

Revenue Recognition Impact:

- Under IFRS 15 (Paragraphs 31-38) and ASC 606 (Step 5), revenue is recognized when (or as) the entity satisfies a performance obligation by transferring a promised good or service to a customer.
- For the first delivery, revenue is recognized as the customer accepted the delivery, indicating that control was transferred.
- For the second delivery, the rejection indicates that control was not effectively transferred, hence no revenue is recognized.
- The overall revenue recognition is affected as follows:
 - Only €5,200,000 out of the expected €15,600,000 (3 quarters) has been recognized.
 - The remaining €15,600,000 stays as a contract liability until the quality issues are resolved and future deliveries are accepted.

Cost Recognition:

- Costs are generally recognized when incurred, regardless of revenue recognition.
- The €2,000,000 cost for the first delivery is recognized alongside the revenue.
- The €2,000,000 cost for the second delivery is recognized as an expense, despite no revenue recognition, as it represents a cost of a failed delivery.

This scenario highlights the importance of robust contract management and quality control processes, as quality issues can significantly impact revenue recognition and profitability. It also demonstrates the need for detailed tracking of each delivery and its acceptance status, which can be effectively managed through SAP ERP's project management and financial modules.

#GOATConsultants™-Level Insights:

For small and mid-tier life sciences companies, adopting modern ERP solutions is not just a matter of improving financial operations—it's a strategic imperative. These systems enable companies to navigate the complexities of licensing agreements, ensuring that they can continue to innovate and bring life-changing therapies to market.

Click the image to read the full article.



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