NIIR PROJECT CONSULTANCY SERVICES

NPCS

CLIENT CASE STUDY

Manufacturing of IV Fluids Using BFS Technology

Enabling a Swiss Pharmaceutical Investment Through Research-Driven Feasibility Analysis

Client: M/s. Dibia Systems GmbH | Location: Switzerland

Industry: Pharmaceutical Manufacturing – Large Scale Investment

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ABOUT NIIR PROJECT CONSULTANCY SERVICES (NPCS)

Niir Project Consultancy Services (NPCS) is a globally recognized industrial consultancy organization headquartered in New Delhi, India. With over four decades of uninterrupted service, NPCS has established itself as Asia's leading industrial knowledge ecosystem, offering world-class advisory to entrepreneurs, investors, and corporations worldwide.

> ***"NPCS is part of Asia's leading industrial knowledge ecosystem with thousands of project profiles and global consulting expertise."***

Core Services

Detailed Project Reports (DPR)

Bankable, investor-grade DPRs covering manufacturing processes, plant economics, raw material analysis, and financial projections.

Techno-Economic Feasibility Studies

Rigorous assessment of technical viability combined with detailed cost-benefit and ROI modeling for new industrial projects.

Market Research & Demand Analysis

Comprehensive market intelligence covering global and regional demand trends, competitive landscape, and growth forecasts.

Engineering Advisory & Strategic Planning

Plant design, machinery selection, implementation roadmaps, and end-to-end strategic advisory for industrial ventures.

NPCS — GLOBAL AUTHORITY IN INDUSTRIAL CONSULTING

For over 30 years, NPCS has empowered entrepreneurs and corporations across six continents to make informed, confident industrial investment decisions. Our track record speaks for itself:

30,000+	50+	30+	250,000+
Detailed Project Reports Published	Countries Served Globally	Years of Industrial Expertise	Industrial Projects Delivered

NPCS serves a diverse client base including individual entrepreneurs, SMEs, large corporations, government agencies, and international development organizations — delivering research-driven insights that reduce risk and accelerate investment decisions.

CLIENT OVERVIEW

Parameter	Details
Client Name	M/s. Dibia Systems GmbH
Project Location	Switzerland
Industry	Pharmaceutical Manufacturing – Large Scale Investment
Project Identified by NPCS	Manufacturing of IV Fluids using BFS (Blow-Fill-Seal) Technology
Consultancy Provided	Techno-Economic Feasibility Study, Market Assessment, Raw Material Analysis, Financial Evaluation, Strategic Advisory
Implementation Status	Client reviewed feasibility findings and proceeding toward implementation planning

Client Investment Objectives

M/s. Dibia Systems GmbH, a Swiss-based enterprise, was seeking to diversify into high-growth pharmaceutical manufacturing. The client approached NPCS with a clear mandate: identify a manufacturing venture that would deliver long-term profitability while aligning with Switzerland's world-class industrial infrastructure and regulatory environment.

Key investment goals included:

- Long-term profitability and sustainable business growth
- Alignment with regional pharmaceutical and industrial infrastructure
- Strong and consistent healthcare sector demand
- Technological efficiency and operational scalability
- Opportunities to serve both domestic Swiss and international export markets

PROBLEM STATEMENT & INVESTMENT CHALLENGES

Entering pharmaceutical manufacturing is among the most capital-intensive and regulation-heavy industrial decisions an investor can make. Without precise, research-backed guidance, even well-resourced companies face significant risks. M/s. Dibia Systems GmbH identified the following key challenges before engaging NPCS:

Market Gap Analysis

The pharmaceutical market is vast but highly segmented. Identifying a product category with sustained global demand, limited local competition, and high barriers to entry required deep market intelligence.

Technology Selection Uncertainty

Multiple sterile manufacturing technologies exist. Selecting BFS over conventional vial filling or blow-molding alternatives requires a thorough comparative assessment of automation levels, contamination risk, throughput, and cost efficiency.

Financial Risk Assessment

Large-scale pharmaceutical manufacturing demands significant capital outlay for cleanroom facilities, specialized BFS machinery, and regulatory compliance infrastructure, with risks of cost overruns if not properly modeled.

Regulatory Complexity

IV fluid manufacturing for clinical use must comply with Swiss Medic, EU GMP Annex 1 (Manufacture of Sterile Medicinal Products), and international pharmacopoeia standards, creating a complex compliance landscape.

Supply Chain Complexity

Securing pharmaceutical-grade raw materials — including water for injection, electrolyte compounds, and sterile packaging inputs — requires robust supply chain validation and vendor qualification processes.

Strategic Positioning

Understanding how to position a new manufacturing unit within the existing Swiss and European pharmaceutical supply chain — including differentiation from incumbent producers and export market access strategies — was essential.

NPCS APPROACH & CONSULTING METHODOLOGY

NPCS deployed a structured, phase-wise consulting methodology to guide M/s. Dibia Systems GmbH from initial project identification through to investment-ready feasibility findings. Each phase was designed to build upon the previous, ensuring a comprehensive and risk-mitigated path to decision.

Phase 1	**Project Identification & Opportunity Screening** NPCS evaluated multiple pharmaceutical manufacturing verticals suitable for the Swiss market. After rigorous screening across product demand, regulatory accessibility, technology maturity, and investment scale, IV fluid manufacturing using BFS technology was identified as the optimal project. The selection was driven by consistently high institutional demand, advanced but commercially proven technology, and strong alignment with the client's investment capacity.
Phase 2	**Market Potential Assessment** NPCS conducted a thorough analysis of global and regional demand for IV fluids and sterile medical solutions. This included assessment of healthcare infrastructure expansion, hospital procurement trends, government health program spending, and export market dynamics. The analysis confirmed strong and growing demand with limited risk of demand-side volatility.
Phase 3	**Technical Feasibility & Process Evaluation** A detailed technical assessment of BFS (Blow-Fill-Seal) technology was conducted. This covered the complete manufacturing process — from raw material receipt and water purification to container formation, filling, sealing, and final packaging. Process flow diagrams, machinery specifications, cleanroom requirements, and utility infrastructure needs were all evaluated.
Phase 4	**Raw Material & Supply Chain Analysis** NPCS evaluated the availability and sourcing of pharmaceutical-grade inputs including raw APIs (sodium chloride, glucose, lactated Ringer's solution components), water for injection (WFI), and BFS-compatible resin materials. Supply chain risks were identified and mitigation strategies recommended.
Phase 5	**Financial Modeling & Investment Viability** A comprehensive financial feasibility model was developed covering capital expenditure estimates, operational cost structure, revenue projections across multiple capacity scenarios, break-even analysis, ROI, IRR, and payback period. Sensitivity analysis was performed to test financial robustness under varying market and cost conditions.
Phase 6	**Strategic Advisory & Implementation Planning** NPCS provided strategic guidance on plant location, regulatory pathway, workforce requirements, and phased capacity ramp-up. A structured implementation roadmap was prepared to guide the client from investment decision through to operational production launch.

SCOPE OF SERVICES DELIVERED

NPCS delivered a comprehensive suite of consulting services tailored to the specific requirements of M/s. Dibia Systems GmbH's pharmaceutical manufacturing investment. The scope was designed to cover every critical dimension from opportunity validation to implementation readiness.

Project Identification

Systematic screening of pharmaceutical manufacturing opportunities in alignment with the client's financial capacity, strategic goals, and the Swiss regulatory and market environment.

Detailed Project Report (DPR)

Preparation of a comprehensive, bankable DPR covering manufacturing processes, plant layout, machinery specifications, capacity planning, raw material sourcing, and investment requirements.

Technical Feasibility Analysis

In-depth evaluation of BFS manufacturing technology, process flows, equipment selection, cleanroom classification, utility requirements (purified water, HVAC, compressed air), and quality control infrastructure.

Market Validation

Analysis of global IV fluid market size, growth trajectory, key demand drivers, competitive dynamics, and Switzerland's position as a high-value pharmaceutical manufacturing hub.

Financial Modeling

Development of detailed financial projections including capital investment breakdown, operating cost structure, revenue forecasting, profitability analysis, break-even calculation, ROI, and IRR assessment.

Plant Layout & Machinery Selection

Guidance on optimal facility layout for GMP-compliant sterile manufacturing, including cleanroom zoning, material flow, personnel flow, and selection of BFS production line equipment from qualified global suppliers.

Implementation Roadmap

Phased implementation strategy covering site selection, facility construction, equipment procurement, regulatory submissions, validation activities, and commercial production launch milestones.

Strategic Advisory

Ongoing consultative support to assist the client in interpreting findings, stress-testing assumptions, and making an informed, risk-mitigated investment decision with full confidence.

TECHNICAL INSIGHTS — BFS TECHNOLOGY & IV FLUID MANUFACTURING

Blow-Fill-Seal (BFS) technology is recognized by regulatory authorities worldwide — including the US FDA, EU EMA, and Swiss Medic — as an advanced aseptic manufacturing process for parenteral products. It enables the production of IV fluid containers in a single, continuous, automated process, significantly reducing contamination risks associated with conventional glass vial filling.

BFS Manufacturing Process — Step-by-Step

01	**Raw Material & API Preparation** Pharmaceutical-grade APIs (e.g., Sodium Chloride, Glucose, Lactated Ringer's components) are received, tested, and weighed according to batch manufacturing records. Water for Injection (WFI) is produced via multi-effect distillation or reverse osmosis.
02	**Solution Preparation (Compounding)** APIs are dissolved in WFI under controlled conditions. pH is adjusted and the bulk solution is filtered through 0.22-micron sterilizing-grade membrane filters to achieve sterility.
03	**BFS Container Formation** Medical-grade polyethylene or polypropylene resin granules are fed into an extruder. The molten parison is formed within the BFS machine under Class A (ISO 5) conditions, with integrated HEPA-filtered laminar airflow.
04	**Filling & Sealing (Single Operation)** The sterile solution is filled into the freshly formed container in a single, closed automated operation. The container is sealed within the same mold cycle — eliminating any open-air exposure and dramatically reducing contamination risk.
05	**Inspection & Quality Control** Sealed containers undergo 100% visual/automated inspection for particulate matter, container integrity, fill volume accuracy, and seal quality. Samples are taken for in-process and finished product testing.
06	**Labeling, Packaging & Dispatch** Approved batches are labeled, assembled into outer cartons, and palletized for distribution. Full batch traceability is maintained from raw material receipt to final product release per GMP requirements.

Key Technology Advantages of BFS

- Fully automated aseptic filling — minimal human intervention
- Integrated container forming, filling & sealing in one cycle
- Class A environment maintained throughout the process
- Suitable for a wide range of IV solutions and volumes
- Superior container integrity vs. glass vials — no breakage risk
- Lower long-term operating costs vs. conventional vial lines
- Recognized globally by FDA, EMA, WHO GMP standards
- High throughput — up to thousands of containers per hour

FINANCIAL & MARKET ANALYSIS

Market Demand & Growth Outlook

The global IV fluids market is a multi-billion-dollar segment driven by the fundamental and non-discretionary nature of demand. IV fluids are classified as essential medicines by the WHO, ensuring consistent institutional procurement regardless of economic cycles.

Key Demand Drivers	Market Indicators
• Rapid expansion of global healthcare infrastructure • Increasing surgical procedure volumes • Aging population requiring critical and long-term care • Rising emergency care and ICU admissions globally • Growth in pharmaceutical supply chains and hospital networks • Government-mandated essential medicine stockpiling	• Global IV fluids market growing at consistent CAGR • Europe remains a high-value, quality-premium market • Switzerland's pharma ecosystem supports premium pricing • Strong export corridors to EU and emerging markets • WHO Essential Medicines List inclusion ensures stable demand • BFS technology commands quality differentiation premium

Investment Overview — Key Financial Parameters

Based on NPCS financial modeling for a BFS-based IV fluid manufacturing facility, the following indicative financial parameters were evaluated as part of the feasibility assessment:

Capital Investment	Project Economics	Strategic Value
• Land & Civil Works • BFS Production Lines • Cleanroom Infrastructure • Utility Systems (WFI, HVAC) • QC Laboratory Setup • Working Capital Reserve	• Positive ROI Projection • Competitive IRR Metrics • Feasible Payback Period • Healthy Gross Margins • Break-even Capacity Identified • Sensitivity Analysis Conducted	• Essential Medicine Category • Government Procurement Access • Export to EU/Global Markets • Technology Barrier to Entry • Long-Term Demand Visibility • Premium Positioning Possible

PROJECT EXECUTION — TIMELINE & MILESTONES

NPCS structured the project evaluation and advisory engagement across clearly defined phases, each with measurable deliverables and milestones. The timeline below reflects the consulting engagement from initial project identification through to client investment decision.

Phase	Milestone	Deliverables & Activities
Phase 1	**Project Identification**	Screening of pharmaceutical manufacturing opportunities; identification of IV fluid manufacturing via BFS technology as the optimal investment for the client's profile and market context.
Phase 2	**Market Research**	Comprehensive global and regional market analysis for IV fluids; demand drivers, competitive landscape, pricing dynamics, and growth projections delivered.
Phase 3	**Technical Evaluation**	BFS technology assessment; process flow documentation; machinery selection; cleanroom and utility requirement evaluation; regulatory pathway mapping.
Phase 4	**Raw Material & Supply Chain**	Pharmaceutical-grade input sourcing analysis; supplier qualification framework; supply chain risk identification and mitigation strategies developed.
Phase 5	**Financial Modeling**	Full financial model developed: CAPEX, OPEX, revenue projections, ROI/IRR analysis, break-even modeling, and sensitivity testing across multiple scenarios.
Phase 6	**DPR & Advisory Report**	Comprehensive Detailed Project Report (DPR) delivered; strategic advisory sessions conducted; client investment decision facilitated.
Outcome	**Investment Decision**	Client reviewed complete feasibility findings and confirmed decision to proceed with implementation planning for BFS-based IV fluid manufacturing facility.

RESULTS & OUTCOMES

The NPCS consulting engagement delivered measurable value across every dimension of the client's investment decision process. The comprehensive feasibility study and strategic advisory provided M/s. Dibia Systems GmbH with the clarity, confidence, and direction needed to commit to a major pharmaceutical manufacturing investment.

Investment Confidence

The client gained a fully validated investment thesis, backed by market data, technical analysis, and financial modeling — eliminating ambiguity and enabling a decisive investment commitment.

Financial Clarity & ROI Visibility

Detailed financial modeling provided a clear picture of capital requirements, operating economics, and return expectations — enabling informed negotiation with financiers and strategic partners.

Technology Risk Mitigation

By selecting BFS over conventional alternatives, the client is positioned to benefit from lower contamination risk, superior regulatory compliance, and higher production efficiency from day one.

Regulatory Pathway Clarity

The client received a structured regulatory compliance roadmap covering Swiss Medic approval requirements, EU GMP Annex 1 compliance, and quality system implementation — significantly de-risking the licensing process.

Strategic Market Positioning

The client is positioned to enter the IV fluid market with a clear competitive advantage: advanced BFS technology, GMP-compliant Swiss manufacturing credentials, and access to EU and international export markets.

Implementation Readiness

M/s. Dibia Systems GmbH moved from initial concept to implementation planning stage — a transformative step enabled entirely by NPCS's research-driven consulting framework and actionable deliverables.

CLIENT TESTIMONIAL

> *The feasibility study prepared by NPCS provided valuable insights into IV fluid manufacturing and the BFS technology ecosystem. Their structured analysis helped us evaluate the project with confidence and move forward with our investment strategy. NPCS delivered exactly the clarity and depth we needed to make this investment decision with full conviction.*
>
> **— M/s. Dibia Systems GmbH | Switzerland**

WHY CHOOSE NPCS FOR YOUR INDUSTRIAL PROJECT

NPCS stands apart from generic consulting firms through its unparalleled combination of industrial depth, research infrastructure, and global reach. Here is why leading investors and entrepreneurs worldwide choose NPCS:

Proven Industrial Expertise

40+ years of hands-on experience across 250+ industrial sectors — from pharmaceuticals and chemicals to food processing, textiles, and advanced manufacturing. NPCS brings domain depth that generic consultants cannot match.

Data-Driven Feasibility Analysis

Every NPCS recommendation is backed by primary research, market data, and rigorous financial modeling. Our feasibility reports are designed to withstand scrutiny from banks, investors, and regulatory bodies.

Global Market Understanding

With clients in 50+ countries and a database of 30,000+ project reports, NPCS offers unmatched global market intelligence — helping clients identify opportunities, understand competitive dynamics, and access export markets.

Risk Mitigation Approach

NPCS's structured methodology systematically identifies and addresses technical, market, financial, and regulatory risks before they can impact your investment — protecting capital and accelerating timelines.

End-to-End Project Support

From initial project identification and feasibility analysis through to implementation planning and operational advisory, NPCS provides seamless support at every stage of the investment journey.

Bankable, Investor-Ready Deliverables

NPCS project reports and DPRs are structured to meet the requirements of financial institutions, development banks, venture funds, and institutional investors — facilitating funding and partnerships.

CONCLUSION

The successful identification and feasibility evaluation of the BFS-based IV fluid manufacturing project for M/s. Dibia Systems GmbH is a testament to the power of research-driven industrial consulting. What began as an investment concept was transformed — through rigorous technical analysis, market research, and financial modeling — into an implementation-ready project with clear strategic and economic merit.

This engagement demonstrates NPCS's unique ability to compress the investment decision timeline, eliminate guesswork, and provide investors with the confidence to commit capital to large-scale industrial ventures. The client's decision to proceed with implementation planning is the ultimate validation of NPCS's consulting methodology and deliverable quality.

For investors and entrepreneurs considering pharmaceutical manufacturing, agro-processing, chemical production, or any industrial venture — NPCS provides the research foundation, technical expertise, and strategic clarity to move from idea to action with confidence.