**The Complete Checklist for Pharmaceutical Companies Entering the French Market**

**Your Guide to Finding and Working with the Right Exploitant**

Pre-Search Phase

Internal Assessment

□ Define your product portfolio for French market entry

□ Identify specific therapeutic areas and special requirements

□ Determine timeline for market entry

□ Assess internal regulatory capabilities

□ Review budget allocation for French market operations

□ Identify key stakeholders in your organization

Regulatory Preparation

□ Verify Marketing Authorization (AMM) status

□ Review pharmacovigilance requirements for your products

□ Prepare product technical files

□ Document quality control requirements

□ List all required regulatory submissions

□ Check batch release requirements

Exploitant Search Phase

Essential Criteria

□ Create shortlist of potential exploitants

□ Verify exploitant licenses and certifications

□ Review experience in your therapeutic area

□ Check pharmacovigilance systems and processes

□ Assess quality management capabilities

□ Evaluate regulatory affairs expertise

□ Review track record with ANSM interactions

Operational Considerations

□ Assess geographical coverage

□ Review IT systems compatibility

□ Check language capabilities

□ Evaluate response times and availability

□ Review standard operating procedures

□ Assess batch release capabilities

□ Verify storage and distribution network

Due Diligence Phase

Documentation Review

□ Request and review quality certificates

□ Check regulatory inspection history

□ Review standard contract terms

□ Assess insurance coverage

□ Verify staff qualifications

□ Review performance metrics

□ Check references from other clients

Compliance Verification

□ Review GMP compliance history

□ Check GDP certification

□ Verify pharmacovigilance system

□ Review SOPs for key processes

□ Assess GDPR compliance

□ Check reporting capabilities

Implementation Phase

Contract Setup

□ Define service level agreements

□ Establish key performance indicators

□ Set communication protocols

□ Define escalation procedures

□ Agree on pricing structure

□ Define termination conditions

□ Establish review periods

Operational Setup

□ Create transition timeline

□ Define product transfer process

□ Set up communication channels

□ Establish reporting templates

□ Define quality control checkpoints

□ Create emergency procedures

□ Plan staff training

Ongoing Management

Monitoring

□ Schedule regular performance reviews

□ Track compliance metrics

□ Monitor adverse event reporting

□ Review quality indicators

□ Check regulatory submissions

□ Assess communication effectiveness

□ Review cost efficiency

Risk Management

□ Maintain risk register

□ Review business continuity plans

□ Update emergency procedures

□ Monitor market changes

□ Track regulatory updates

□ Review insurance coverage

□ Assess competitive landscape

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Need Expert Guidance?

This checklist covers the essential elements of finding and working with a French exploitant, but every company's situation is unique. At Elliogen, we specialize in matching pharmaceutical companies with the perfect exploitant partner - at no cost to you.

Contact us to ensure you make the right choice for your French market entry.

Download our complementary resources and guides at www.elliogen.com