

Start-up Quick-check

Table of contents

- I. What is this start-up quick-check for?
 1. Product Freedom-to-operate?
 2. Manufacturing?
 3. Distribution?
 4. Logistics?
 5. Regulatory requirements?
 6. Founding team
 7. Time to market entry?
 8. Critical contractual partners?
 9. Burn rate?
 10. Financing?
 11. Exit plan
 12. Anything else?

I. What is this start-up quick-check for?

This start-up quick-check is designed to help founders prepare their start-up and, above all, to help them quickly gain an overview of their project. The quick check is aimed at founders in the early phase of the project with a product idea. The quick-check is based on a physical product, e.g. from the fields of medical technology or life sciences. This can be, for example, a surgical light or similar medical device regulated under the EU-MDR or, for example, a "research use only" product.

The questions in the quick-check are designed to help founders examine their project from different perspectives, identify strengths and weaknesses of the project in order to adapt or improve plans or identify and initiate countermeasures.

1. Freedom-to-operate (FTO) product

1. Is the core idea of the product protected by a patent?
2. Do you have your own patents/licenses?
3. Do the existing IP rights provide effective third-party protection?
If so, how long?
4. Is the ownership of the IP/rights/product idea clear?
5. Is the financing of the maintenance of property rights secured in the long term?

2. Manufacturing of the product

1. Is in-house production or production by a third party required?
2. Do you need adapted machines/special equipment/investments?
3. Is there sufficient capital for any necessary adjustments of machinery, tooling etc.?
4. Can production development be outsourced?
5. Are the regulatory requirements, e.g. EU-MDR, reliably fulfilled by the developers (e.g. documentation) and manufacturing partners?
6. Are multiple versions of the product required to e.g. adapt for different local installation requirements electrical grid conditions etc.

3. Distribution

1. Which target markets will be addressed with the product?
2. Is there a possible sales channel that fulfills/can easily fulfill the regulatory requirements?
3. Could the product be successful in an online sales model?
4. Does the product require maintenance, is there a service, training expense/revenue stream?

4. Logistics

1. Are there special logistics requirements/ complex logistics (cooling etc.)
 - during production
 - during distribution (e.g. during installation, set-up in the clinic)

5. Regulatory requirements

1. What are the requirements for the product in the target markets?
2. Its production? Quality assurance systems, ISO 13485, 9001 etc.
3. Are there regulatory demands on the sales organization? E.g. local registration of the sales organization
4. Its service decentralized in the market/centralized by the start-up itself?

6. Founding team

1. What tasks can the founding team do itself?
2. Which skills need to be sourced from third parties?
3. Is the distribution of tasks among the founders determined/agreed?
4. Is the capital participation determined/agreed?
5. Are the interests aligned for the benefit of the project?
6. Can the founders each bear the business risk?

7. Time to market entry

1. What is the worst assumed timeframe for the product's market entry?
2. What is the best-case scenario for market entry?
3. Can/would project partners go along with this project duration?

4. How long would the product be patent-protected in the worst case?

8. Critical contractual partners?
 1. Development (development contract)
 2. Production (production contract, framework supply contract)
 3. If applicable, clinic (not for "research use only") or CRO
 4. Marketing (Agency)
 5. Distribution (representative, importer, agent)
 6. Logistics
 7. Service
 8. Regulatory
 9. Taxes

9. Burn rate
 1. What burn rate is expected for the anticipated course of business/project?
 2. How does the burn rate develop in the worst case?
 3. What countermeasures/capital buffers etc. can be planned?

10. Financing
 1. Is the financing for the development in place?
If not. Which partners could co-finance the project?
 2. Are subsidies available at reasonable conditions?
 3. Are contacts to financing partners available if the development is successful?

11. Exit plan
 1. What is the planned exit/long term scenario re the founders?
 2. What interests are the founders pursuing with the start-up?
 3. Are there any strategic partners who might be interested in the product/business?

12. Anything else?

1. Are there any other important risks/benefits that should be considered?
2. What effects can be anticipated from external factors that should be taken into account/monitored (customs, interest rate or regulatory developments, etc.)?

Do you have any questions, need German/EU legal advice or would you like to give me your feedback? Feel free to call or write, I look forward to hearing from you. Please make an appointment for a personal visit.

Matthias Mock
Attorney at law (Germany)



mock.legal
Gartenstrasse 14
78567 Fridingen an der Donau
Germany

www.mock.legal
E: info@mock.legal
T: +49 7463 2671 649
M: +49 1556 0888 308

This client information does not constitute legal advice. Status of the information: May 22, 2025.
If you find any errors or omissions, please bring them to my attention.

© 2025 Matthias Mock, Attorney at Law (Germany). All rights reserved.