Bpath
BioEngineering & Business Consulting

BENEFIT FROM BPI FINANCING FOR YOUR NEEDS OF CONSULTING AND SUPPORT

The technical documentation for some of your devices may need to be to comply with regulatory (EU) 2017/745?

As part of France 2030, **BPI can cover 50% of the cost of a referenced expert.**

What is covered?

If your project involves an innovative medical device or digital health solution, 50% of the cost of services can be covered to help you meet the regulatory and clinical demonstration challenges that are essential for market access.

The support must be provided by a referenced expert and can cover three areas:

1. Implementation of a quality management system [SMQ] meeting requirements of standard ISO13485;
2. The establishment of a CE marking dossier [DT] for class IIa, IIb or III, or class B, C, D IVD-MD, as well as the clinical study protocols for the dossier;
3. Designing a clinical or medico-economic study and redaction of the related protocol.

Within Bpath, Richard Minfelde, is referenced for area 2: Technical Documentation (intuitu personae referencing). Other consultants may be recommended for the QMS or a clinical study.

How does it work?

Once a need for support has been expressed, Bpath will draw up an offer so that the Client can submit a request on the BPI platform dedicated to the Diag Medical Device.
In addition to the offer, the company must provide a certificate of social regularity, a certificate of tax status and tax returns.

After approval by BPI France, the Service can be ordered and started.

At the end of the Service, the company pays 50% of the expert's fees and answers the satisfaction questionnaire sent by BPI France. France.

Up to which amount?

Coverage (50% of the Services) varies by areas (1 to 3. as presented before) and device class from : €4,000 ex-VAT (QMS Quality training) to €50,000 ex-VAT (Class III DM support)

More information?

Reach me! **richardminfelde@bpath.eu** ; +33 1 42 00 16 99

Richard **M**infelde, PhD. After more than 15 years of R&D/industrialization in orthopedic and spinal devices, he created Bpath in 2012 to meet the needs of non-active DM manufacturers and project developers in regulatory and technical fields. He supports Clients in producing technical data in response to new regulatory requirements.