

Clinical Evaluator Requirements:

The MEDDEV 2.7.1 Rev. 4 guidance on clinical evaluations states the following:

The clinical evaluation should be conducted by a suitably qualified individual or a team. The manufacturer should take the following aspects into consideration:

The manufacturer (Balmonds Skincare) defines requirements for the evaluators that are in line with the nature of the device under evaluation and its clinical performance and risks.

The manufacturer (Balmonds Skincare) should be able to justify the choice of the evaluators through reference to their qualifications and documented experience, and to present a declaration of interest for each evaluator.

As a general principle, the evaluators should possess knowledge of the following:

- research methodology (including clinical investigation design and biostatistics);
- information management (e.g. scientific background or librarianship qualification; experience with relevant databases such as Embase and Medline);
- regulatory requirements; and
- medical writing (e.g. post-graduate experience in a relevant science or in medicine; training and experience in medical writing, systematic review and clinical data appraisal).

With respect to the particular device under evaluation (Skin Salvation), the evaluators should in addition have knowledge of:

- the device technology and its application;
- diagnosis and management of the conditions intended to be diagnosed or managed by the device (eczema and psoriasis), knowledge of medical alternatives, treatment standards and technology (e.g. specialist clinical expertise in the relevant medical specialty).

The evaluators should have at least the following training and experience in the relevant field:

- a degree from higher education in the respective field and 5 years of documented professional experience; or
- 10 years of documented professional experience if a degree is not a prerequisite for a given task.