



Solutions

## Do you face a quality problem on a marketed product?

CEBIPHAR assists you in its diagnosis and resolution and allows you to concentrate on your other priorities.

- + A non-compliant result
- A new peak on a chromatogram
- A change in stability behavior
- A change in the kinetics of dissolution
- An abnormal appearance or smell

... so many unexpected - and by definition unplanned - problems which very often disrupt your organisation. The consequences can be significant for your company (production shutdown, batch recalls) or suspension of marketing of a product. A solution must be found as soon as possible.

- + CEBIPHAR has a technical and regulatory expertise coupled with an experience of 38 years in formulation and analyses (physico-chemical, pharmaco-technical and microbiological). CEBIPHAR supports these issues through an established methodology:
  - Comprehensive investigation of the problem
  - Assumptions about the causes/action plan
  - Analytical or formulation work if necessary
  - Writing of variations if necessary

### Our assets

- A regulatory experience combined with an analytical and galenic expertise
- A sophisticated technical platform:
- physico-chemistry laboratory
  - microbiology laboratory
  - stability storage infrastructure