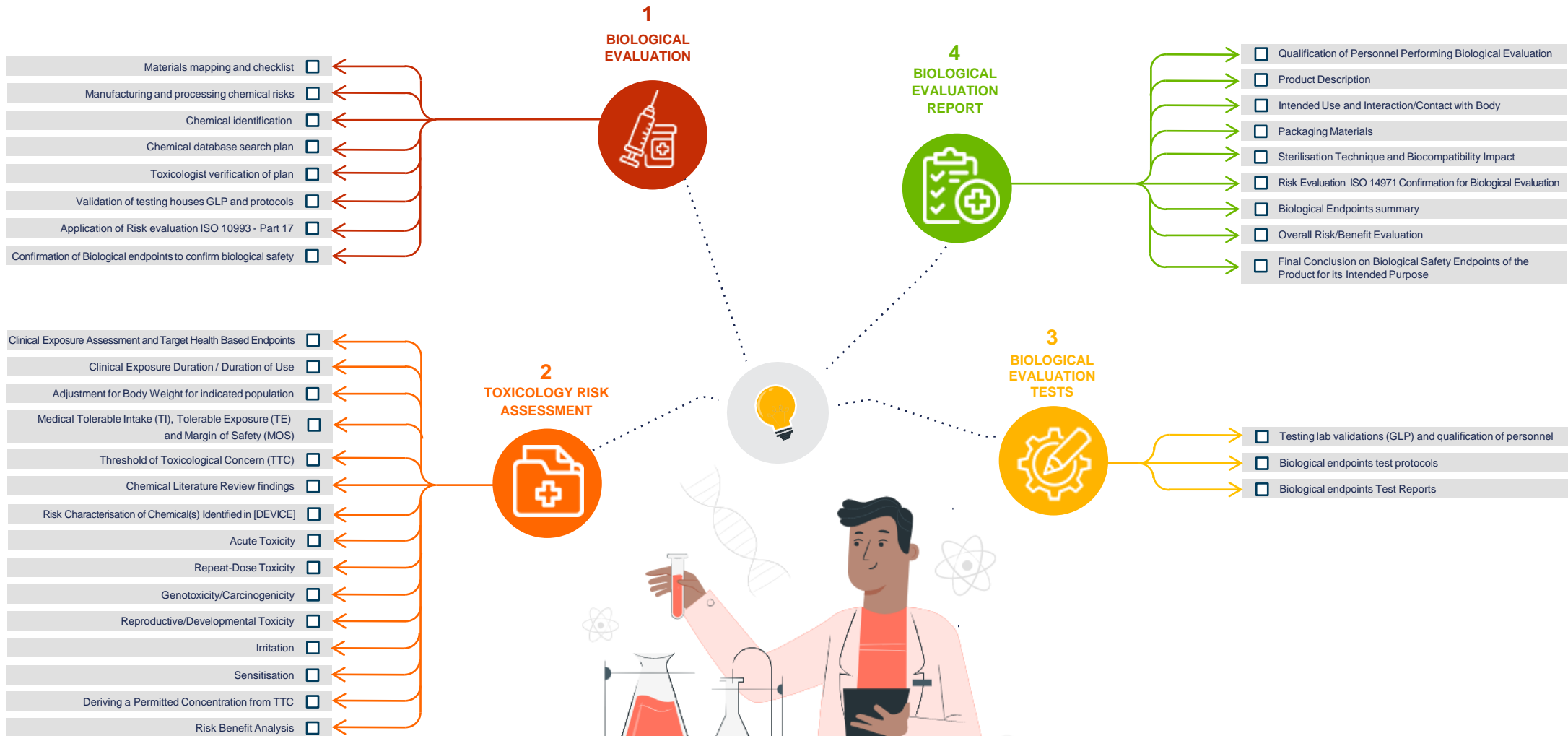


# BIOLOGICAL EVALUATION

## ACCORDING TO MEET MEDTECH INTERNATIONAL MARKET NEEDS (FDA, EU, ext)

Both EU MDR and FDA requires detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user;



### Contact us

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