FMEA analysis on a “pilot process” to validate aptamers as therapeutic purposes

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Quality principles and methodologies can strongly support the management of scientific research, in both basic and applied research laboratories, where procedures and results are rapidly changing and can hardly be standardized. The "Quality and Project Management OpenLab" (q-PMO) CNR Research project, aims to identify, develop and test models of quality management that can strongly support the management of scientific research. In this view, Quality methodologies, such as Failure Mode and Effect Analysis - FMEA, was borrowed from the industrial field, where it is widely used in risk control and process optimization procedures, to validate and support research activities and results, to create a standard and controlled workplace, and to support the interaction between research and industrial application. Aptamers represent attractive targets for cancer diagnosis or therapy and therefore are subjected to intensive investigation and interest of technology transfer. We applied FMEA analysis on a “pilot” process, developed for the selection of cell-specific aptamers, in agreement with the needs of companies interested in the development of this methodology.
This quality approach led to several major advantages. At first, a set of improvement actions was generated covering most lab aspects, such as management of instrumentation or training of personnel involved. Then, FMEA methodology contributed to the definition of good laboratory practice, provided a strong support for the streamlining of protocols and was useful for generating information suitable for knowledge management. The use of a common language oriented towards results is expected to facilitate technology transfer, thus promoting interaction between research and industrial applications.

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