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There is an expanded and more lengthy process of product approval because FDA has significantly increased the scope and complexity of the review process. These actions have led to much more uncertainty surrounding the regulatory process and have significantly increased the financial investment and time required to develop and commercialize new medical products. The net result of these policies has been significant delays in the approval of new products. It now takes a company more than two years, on average, to obtain f.e. pre market approval. Often, the process takes much longer. Review times have also climbed steadily.

(from: A. H. Magazine, "The Impact of Regulation", in: Medical Device Technology, March 1997, pp. 38 ff, ISSN 10 48 - 66 90)

Software Quality Assurance



	Taxangou Lhangou Lhang
Trends	
☐ Globalisation: verifications have changing national standards.	re to be uncomplicatedly adapted to
 Safety critical funtions in softw hardware as well as software. 	are: verifications have to record
☐ Increasing system complexity:	automation
☐ Systems with dependent optime interactions, e.g. between available.	nisation goals: consideration of ilability and safety
☐ Increasingly object-oriented so	oftware development
tware Quality Assurance	software engineering dependability of Prof. Dr. Liggesmeyer,



