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| Organization Name: Company XY (AB employees) | |
| 1 | Participant:  Role: |
| 2 | Scope:  In vitro diagnostic medical device (2017/746)  Medical Device (2017/745)  Does your device include software  Yes  No  Accesories |
| 3 | What is your opinion on the reasons behind the new regulation? |
| 4 | What are the implications/influences of the new regulation in your product portfolio?  *<Please, fill free to change the list of implications that applies to your organization or indicate if any is not applicable (NA >*   |  |  | | --- | --- | | Implications | Opinion | | product reclassification |  | | management of resources |  | | management of people |  | | change in quality procedures |  | | update of agreements with economics operators |  | | discontinuing products |  | | Other, please explain: |  | |
| 5 | In your opinion, what are the pitfalls of the regulation? Are the requirements clear to you? |
| 6 | What are the challenges of your quality management system (QMS) to align with the new regulation? |
| 7 | Does your QMS have the following procedures in place?  a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;  identification of applicable general safety and performance requirements and exploration of options to address those requirements  responsibility of the management;  resource management, including selection and control of suppliers and sub-contractors  risk management  performance evaluation, including PMPF (post-market performance follow-up)  product realisation, including planning, design, development, production and service provision  UDI  setting-up, implementation and maintenance of a post-market surveillance system  handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders  processes for reporting of serious incidents and field safety corrective actions in the context of vigilance  management of corrective and preventive actions and verification of their effectiveness;  processes for monitoring and measurement of output, data analysis and product improvement. |
| 8 | What are the estimate cost and time of implementing the new regulation? Could you provide a gross estimate or indicate where you will need to invest the most?  *<Please, fill free to change the list of requirements that applies to your organization or add the requirements that are the most critical for your product or indicate if any is not applicable (NA)>*   |  |  | | --- | --- | | Requirement | Estimates | | Manufacturer obligations (QMS) | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | person responsible for regulatory compliance | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | implant card | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | requirements regarding design and manufacture | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | requirements regarding the information supplied with the device | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | performance evaluation and performance studies | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | safety and clinical performance | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | clinical investigation | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | Physico-chemical characterization and microbiological, biocompatibility, mechanical, electrical or non-clinical toxicological testing | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | technical documentation | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | notify body | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | post-market surveillance | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | periodic safety update report | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | vigilance | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | specific requirements related to the classification of the device | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | | other, please add | 0-10 K Euro 10-50 K Euro  50-100 k over 100 K Euro | |
| 7 | What are your top-ten tools and practices in your QMS that you considered can be useful for newcomers to the field of medical devices? (e.g. FMEA for process, agile methods, list all requirements as checklist etc.) |
| 8 | Do you think that innovation will be hindered with the new regulatory requirements? |

Please, send the questionnaire to perez.susan.fi@gmail.com