assessment of some 1 B type variations as 1A type variations for API and excipients – in cases when limits and requirements are tightening, and taking into account that Marketing Authorizations Holder is responsible for classification of changes, risk evaluation and that his further activities are under GMP control.. Our proposals does not touch sterile products and practically not – dosage forms

Proposals to reduce extra control and simplify variations regulations are attached.

Best regards,

J.Romanovskis
Head of the board

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