

Update on eSubmissions in Balkans

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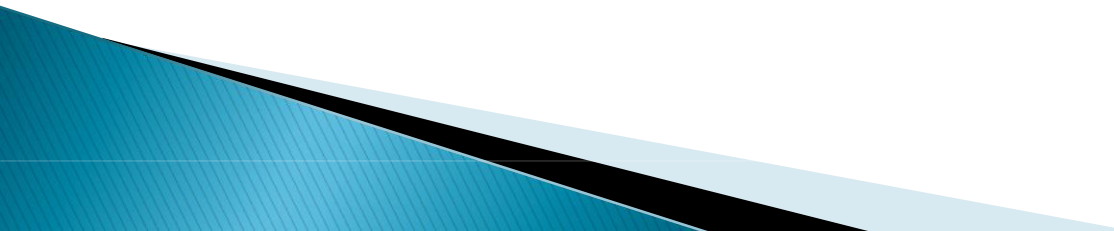
Disclaimer

I am an employee of Bionika Pharmaceuticals

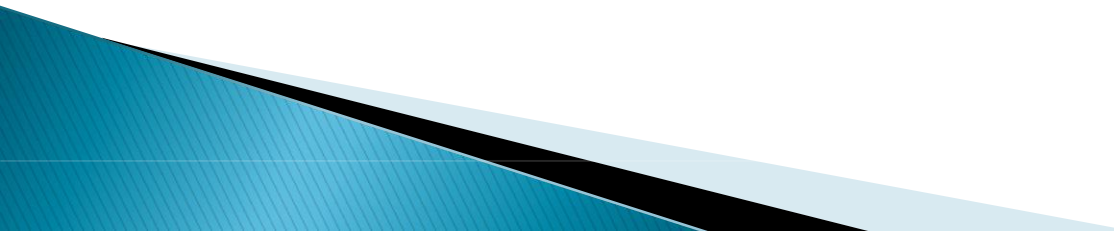
I have about 20 years regulatory affairs & pharmacovigilance practice

Previously, I spent 5 years in chemical business

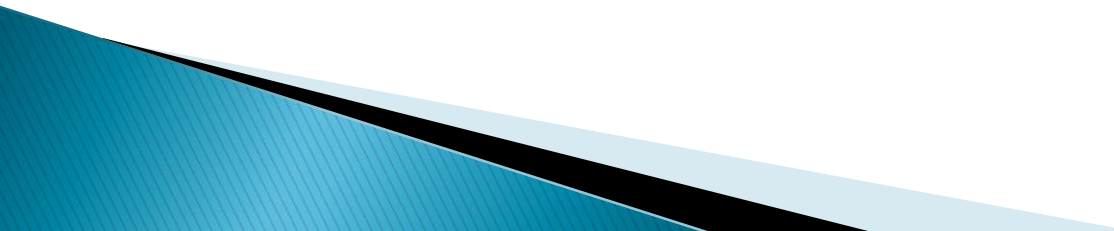
This presentation represents my personal view and is not necessarily the position of Bionika Pharmaceuticals



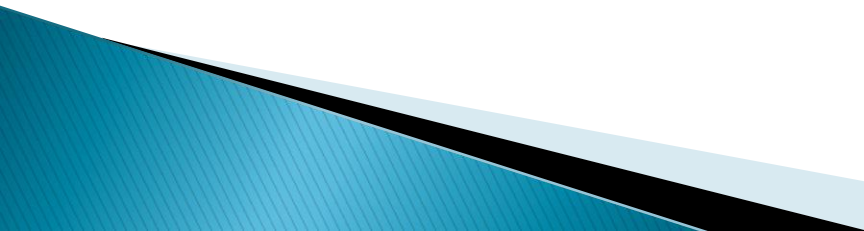
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Global aspects – the future

- In EU eSubmissions of medicinal products are mandatory for all types of Applications
 - Some regional National Agencies have developed customized softwares for electronic submissions, but also documents in NeeS and eCTD format can be used
 - It is expected that all countries will develop similar network and management system in the near future
 - Dynamic Submission Management – evolution of pharmaceutical regulation
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Conclusion

- Regional aspects are moving towards Global aspects - Harmonisation
 - In “near” future eCTD format is expected to be mandatory for all submissions
 - Benefits: data quality, structured content, reusability, faster access, more office space
 - Submission of products for obtaining marketing authorization by companies must be planned early in the product life cycle and in accordance with the current country regulation for specific product category
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THANK YOU FOR YOUR ATTENTION !

QUESTIONS ?

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