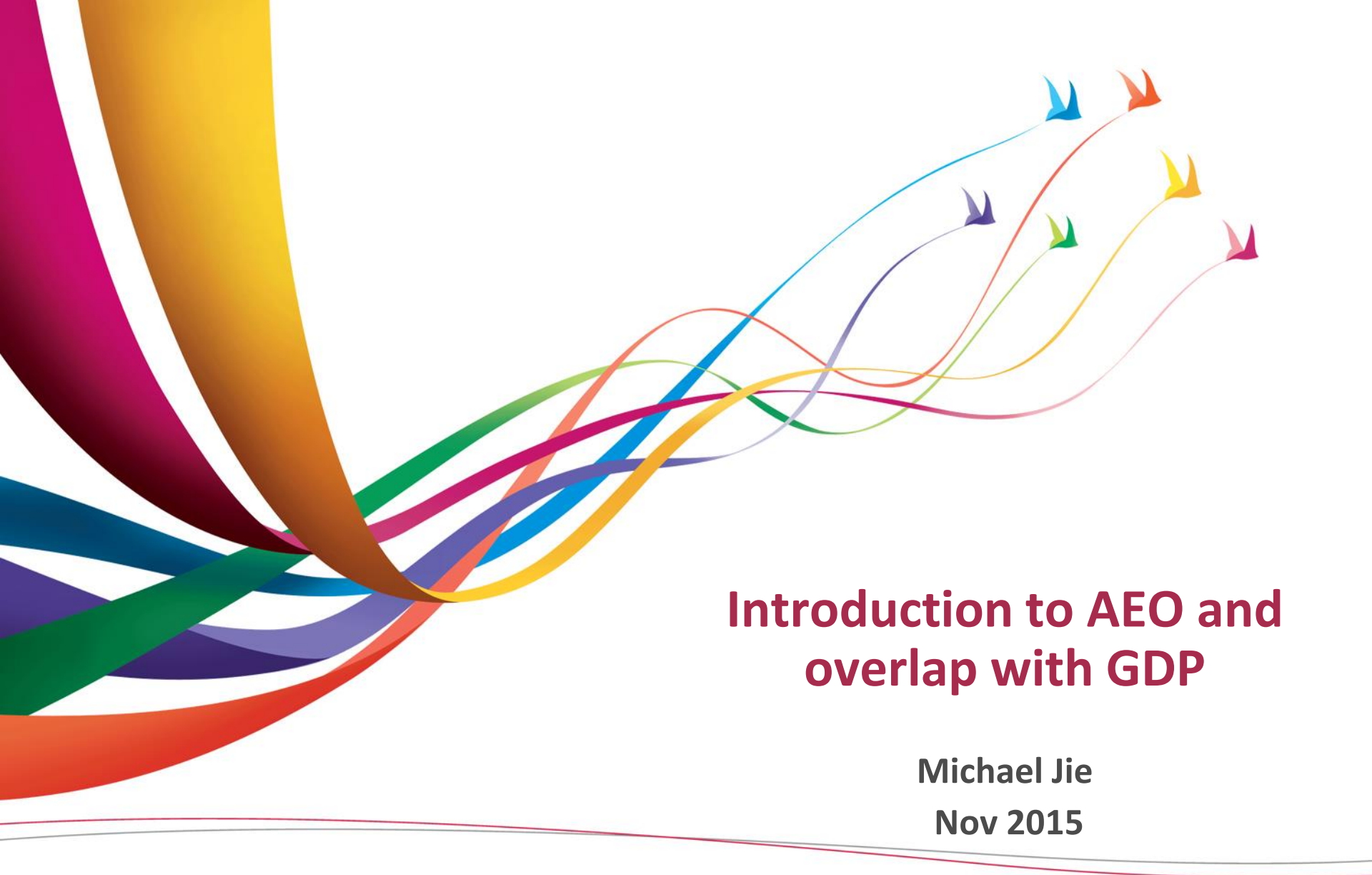


An abstract graphic on the left side of the slide features several thick, curved lines in shades of magenta, yellow, orange, blue, green, and purple. These lines flow from the top left towards the center. From these lines, several thinner, curved lines branch out towards the top right, each ending in a small arrowhead pointing in the same general direction. The overall effect is one of dynamic movement and growth.

Introduction to AEO and overlap with GDP

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Content

- Background of AEO* and GDP#
- Driver for AEO and GDP
- Why AEO and GDP
- Implementation of AEO at Astellas
- Example of changes that were required

*Authorized Economic Operator

#Good Distribution Practice

Background of AEO (Authorized Economic Operator)



- Customs used to be tax-focussed
 - 2001 terrorist attacks focus changed to safety and security
 - Additional focus on safety and security
 - Increased globalization & volume
- logistical complications



Background of AEO

- Balance of safety and commerce
- Asks for a new approach of EU customs (enforced in May 2016)
 - Unknown streams
 - Safe streams (AEO Certified!)



- AEO certified companies are trusted partners of customs
- Customs expect AEO certified companies to mitigate risks

What risks should be mitigated? ⁴

Background of AEO: Examples of risks

- Risks examples from customs perspective
 - Smuggling: Illegal goods (e.g. drugs) are added to a shipment with regular goods
 - Terrorist attacks: goods (e.g. bombs) are added to a shipment with regular goods
 - Tax evasion



Customs expectation: Take ownership in safety and security

- Customs expects AEO certified companies:
 - To communicate important changes related to AEO
 - To register and follow up on incidents
 - To be in control of their own compliance
 - Regular self assessments
 - To do risk analysis

- New GDP guideline introduced in 2013 replacing older guideline from 1994
- Guideline changed from 4 pages to 20 pages:
 - Take into account “recent advances in practices ” for storage/distribution
 - Prevention of the entry of falsified medication in the legal supply chain (2011/62/EU)

Driver for AEO compared to GDP

AEO	GDP
•Safety and security •Tax compliance	•Shipment traceability •Maintaining product quality •Reducing the risk of falsified medication
SCOPE: All goods traffic in/out EU	SCOPE: Medication warehousing & distribution National/International

Why AEO and GDP?

AEO	GDP
Simplified customs procedures	
Less physical checks on shipments	
If checked, it will be announced before delivery and it can be done on a suitable location as defined by the company	
Priority if physical check is needed.	
Mutual recognition (incl. USA/JPN)	
Image – seen as trusted partner for other companies	
→ Less delays due to customs	

Requirements AEO and GDP

AEO	GDP
No past history of customs incidents	Quality management
good trade administration	Personnel
Financially solvable	Premises and equipment
Safety and security measures fit for purpose (risk based)	Complaints, returns, suspected falsified medicinal products, recalls
	Operations
	Documentation
	Outsourced activities
	Self inspections
	Transportation
	Brokers

Set up of the AEO-project within Astellas

- Scope: APEBV&APIBV: Meppel plant, CTM Manufacturing
- Project is managed by supply chain department
- Work packages:
 - Customs
 - Logistics
 - Finance
 - Safety & Security
 - CMO
 - Procurement
 - Production
 - Master data management
 - HR
 - Maintenance

AEO-project within Astellas

- Initial screening done by consultants
- Self assessment questionnaire

Level	
0	No controls, no process awareness
1	Processes unpredictable, poorly controlled and reactive
2	Processes are understood and can be repeated but not documented
3	Processes are documented & standardised across the organisation
4	Processes measured and controlled
5	Continuous process improvement from quantitative feedback, internal controls are integrated

- Risk analysis done on gaps
- Execute mitigating actions
- Acceptability test

Practical example 1

Material ready for shipment is temporarily stored in a room (shared with other departments) until picked up by the courier.

- Risk from AEO perspective:
 - While the material is stored, additional (illegal) goods can be added to smuggle past customs
- Risk limiting factors in place:
 - The room is in a restricted access area
 - Material is stored only for a short period in this shared area
- Additional actions taken:
 - A safety screening is set up by HR for employees that get access to this type of areas.
 - A special tamper evident tape is procured to seal shipment boxes
 - A seal integrity check is done before shipment

→ Also applicable for GDP (exchanging with falsified medication must be prevented)

Practical example 2

How are incoming goods recorded?

- Risk from AEO perspective:
 - Detection of smuggling.
- Risk limiting factors in place:
 - Incoming goods are visually inspected on label, seal integrity and are booked in on the material number corresponding to the supplier material number. Also incoming goods are sampled for ID and can only be used in production after release.
- Additional actions taken: n/a

→ Measures taken for GMP/GDP also covered this AEO requirement

Practical example 3

SOP's are GMP/GDP driven. Stakeholders are QA and the related departments

- Risk from AEO perspective:
 - Changes to SOP's related to warehousing and distribution may cause a situation that is non-compliant with AEO guidelines.
- Additional actions taken:
 - A person responsible for AEO within Astellas is appointed. This person will also be stakeholder of AEO related SOP's

→ Measures taken for GMP/GDP not sufficient for AEO

Practical example 4

Private packs are received at Astellas service desk

- Risk from AEO perspective:
 - Materials could be smuggled into the EU/Netherlands via this route, since Astellas will be AEO Certified less physical checks are done.
- Additional actions to be taken:
 - Options:
 - Only allow private shipments where Astellas is not on the address label (all other packs will be checked)
 - Do not allow this type of service
 - ...

→ Not applicable for GDP

Summary

- AEO and GDP have a different driver
- Scope is different
- GDP is mandatory, AEO certification is not
- Some overlap is present making implementation more easy



Relevant guideline/directive for example



AEO:

Artikel 14 *duodecies*

“1 c) er zijn maatregelen genomen om het toevoegen, omwisselen of wegnemen van materialen, of andere manipulaties van de goederen bij het laden, lossen, de op- en overslag te voorkomen;

1 f) de aanvrager onderwerpt sollicitanten voor veiligheidsgevoelige functies aan veiligheidsonderzoeken, voor zover de wetgeving dit toelaat, en verricht regelmatig achtergrondcontroles;

GDP:

5.1. Principle

“The wholesale distributor should use all means available to minimise the risk of falsified medicinal products entering the legal supply chain. “