
IPA
INNOVATION. QUALITY. GLOBAL REACH.
10TH GLOBAL PHARMACEUTICAL QUALITY SUMMIT
NAVIGATING THE NEXT DECADE OF GLOBAL EXCELLENCE

Regulatory Perspectives for Driving Sustainability

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28 February 2025 IPA 10th Global Pharmaceutical Summit

European Directorate for the Quality of Medicines & HealthCare

Council of Europe

EDQM

- ★ Founded in **1964**
- ★ Partial agreement
  (39 members states & the EU
  + 33 observers)
- ★ Contributes to **public health and access to good quality medicines and healthcare in Europe**
- ★ Wide scope of activities

* EU: European Union; TFDA: Taiwan Food and Drug Administration; WHO: World Health Organization

Our vision

Together for better health, for all

Our mission

To contribute to public health protection by engaging with an international community of experts and stakeholders

Key figures

10 Administrative entities

More than **400 staff members** **about 30 nationalities** and dozens of different professions

3 sites

Strasbourg (2)

Metz

4 Areas of work

- ★ Medicinal products
- ★ Substances of Human Origin
- ★ Pharmaceutical care
- ★ Consumer health

Working with a global network of almost **2 000 experts** from a wide variety of scientific disciplines

- ★ **5** intergovernmental committees
- ★ **1** treaty-based body, the European Pharmacopoeia Commission
- ★ **2** steering committees (BSP, CEP)
- ★ **2** networks (OMCL, OCCL)
- ★ More than **100** expert groups

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EDQM and its partners

More than 60 years of collaboration in the field of medicinal products
More than15 years of collaboration in the field of SoHO

World Health Organization

European Union & its bodies

- ★ European Commission
- ★ European Medicines Agency
- ★ European Centre for Disease Prevention and Control

National authorities in Europe and beyond

Agenda

- ★Council of Europe’s roadmap for sustainable development
- ★Sustainability and its incorporation into the EDQM strategic framework
- ★Sustainability of API manufacturing

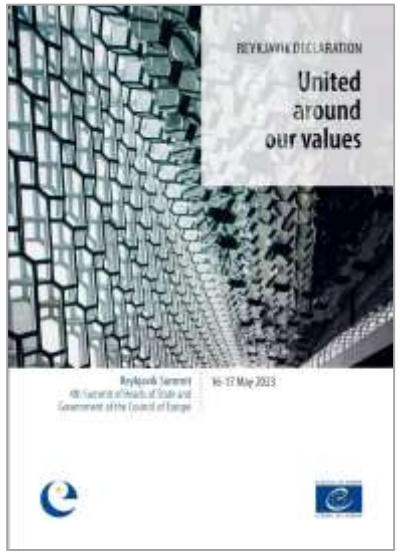
★Council of Europe’s roadmap for sustainable development

★Sustainability and its incorporation into the EDQM strategic framework

★Sustainability of API manufacturing

Council of Europe's roadmap for sustainable development

4th Summit of Head of States
held in **Reykjavík** on 16 and 17 May 2023



Reykjavík Declaration: Commitment to strengthen the Organisation's work on aspects of the environment

More information
Dedicated webpage

Roadmap for sustainable development and carbon footprint reduction

- ★ Council of Europe to become **Carbon neutral by 2050**
- ★ Audit conducted in 2024 to determine the Organisation's Carbon footprint
- ★ Action plan at Organisational level

EDQM as part of its Medium-Term strategy 2024-2027, already on the move:

- ★ Strategic projects to embrace environment sustainability internally and externally

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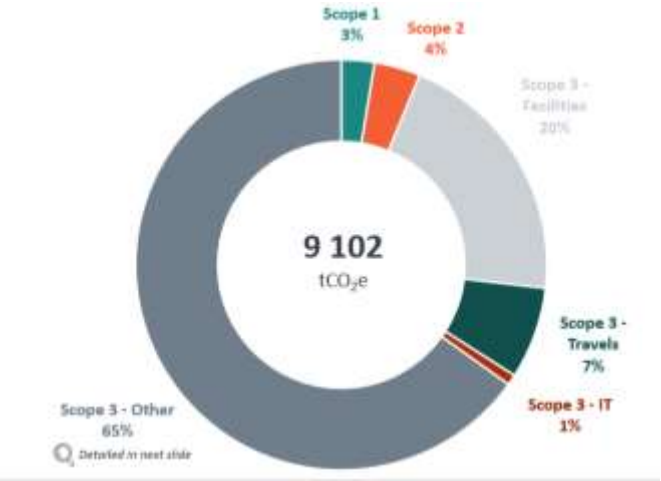
Council of Europe's roadmap for sustainable development Cont.

Main Drivers of EDQM carbon emissions



KEY TAKEAWAYS

- EDQM's emissions are **strongly influenced by its production activity.**
- Downstream freight and emissions directly related to its products (use, end-of-life) account for **49%** of total emissions.
- Scope 3 is also driven up by **product use** and **purchases of raw materials** (especially plastic packaging).
- Scope 3 Facilities includes **renovations** (heavy or light) carried out in buildings occupied by EDQM and furniture purchases.
- **Scope 3 IT** account for only 1% of the total impact.

Next steps

- **Action plan to be adopted by Committee of Ministers**
- **Specific actions are being developed** (e.g. replacement of specific high emission fluids, replacement of plastic and other petrol sourced material notably in shipping material, grouping regular shipments, launch initiatives in circular economy like reusing some material and equipment, using second-hand equipment, etc.).

★Council of Europe’s roadmap for sustainable development

★Sustainability and its incorporation into the EDQM strategic framework

★Sustainability API manufacturing

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EDQM Medium-Term Strategy for 2024-2027

1. Responsiveness	We will respond to and/or address current and emerging public health challenges and priorities for the benefit of patients and consumers.
2. Global Outreach	We will enhance the global outreach and impact of the EDQM.
3. Stakeholder Engagement	We will actively engage with our stakeholders to increase trust and credibility, improve decision-making, and ensure the sustainability of the organisation.
4. Sustainability	We will ensure a sustainable EDQM by future-proofing our operations and activities.
5. Modernisation	We will modernise our working methods to increase the quality and efficiency of our contribution to public health.
6. People Development	We will develop our people, our teams, and our organisational culture to achieve our goals.
7. Culture of Service	We will establish and enhance a culture of service.

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Sustainability at the EDQM

4. Sustainability

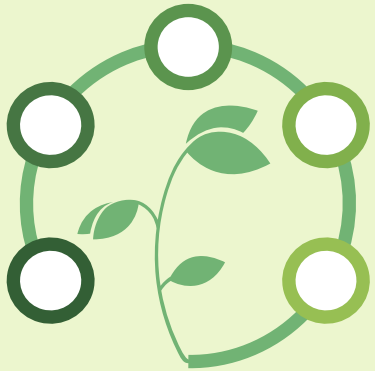
We will ensure a sustainable EDQM by future proofing its operations and activities – 6 projects

Assets/Equipment & Infrastructure

- ★ Future proofing our infrastructure (construction of a 3rd building and refurbishing/renovating existing building)

Employees

- ★ Moving towards workforce planning to ensure sustainability in our workforce



Environment & health

- ★ Environmental sustainability within our organisation (internal)
- ★ Environmental sustainability within our activities for our stakeholders (external)

Stakeholders

- ★ Consolidating & future proofing our IT architecture and tools

Business model

- ★ Securing the EDQM's long term financial sustainability

Examples of concrete actions/approaches towards our users

- ★ **Avoid and reduce use of hazardous reagents**
  e.g. replacing hexane by heptane, reduce use of chloroform and dioxane
- ★ **Reduce the amounts of solvents**
  used in Ph. Eur. methods
- ★ **Avoid use of Mercury (Hg) and mercury compounds** (e.g. mercury salts in non-aqueous titration) and the use of equipment using mercury (e.g. thermometer); supported by Minamata convention (UN) signed by most Ph. Eur. Members

Examples of concrete actions/approaches towards our users Cont.

★**Develop and promote alternatives to Animal Testing** i.e. follow 3Rs approach

Recent **European Pharmacopoeia Commission (EPC)** milestones

- **June 2024**: Removal of the **Rabbit pyrogen test** from 57 texts of the European Pharmacopoeia
  More info: EDQM dedicated news

- **November 2024**: suppression of the Rabbit pyrogen test itself (chapter 2.6.8). Together with 2 other general animal safety tests: Histamine (chapter 2.6.10), Depressor substances (chapter 2.6.11)
  More info: EDQM dedicated news

- **From January 2026**
  No more general safety tests using animals in the Ph. Eur.!

More information: Dedicated webpage

Sustainability as a topic at International Meeting of World Pharmacopoeias

- ★ Discussions on **sustainability** have started also at the **IMWP**
- ★ 14th meeting, pharmacopoeias provided an update on their efforts

Agreed action points:

Develop a set of principles on sustainability for IMWP members to commit to.
- This activity would be conducted by the existing sustainability subgroup, which is co-chaired by the Indian Pharmacopoeia Commission and the US Pharmacopeia. Other participants of the subgroup are the Brazilian Pharmacopoeia, British Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia, Korean Pharmacopoeia and Mexican Pharmacopoeia. Other pharmacopoeias were welcomed to join the subgroup and told they could do so by contacting the Indian Pharmacopoeia Commission or US Pharmacopeia.

Use the agreed principles to develop an advocacy document, for example a white paper, to showcase the sustainability initiatives of world pharmacopoeias.
- This activity would be a continuation of the activity above and would be conducted by the sustainability subgroup.

Next steps

- ★ Discussions continued at 15th meeting taking place (5-7 February 2025) in New-Delhi, India.

More information:
Link to 14th meeting report

- ★Council of Europe’s roadmap for sustainable development
- ★Sustainability and its incorporation into the EDQM strategic framework
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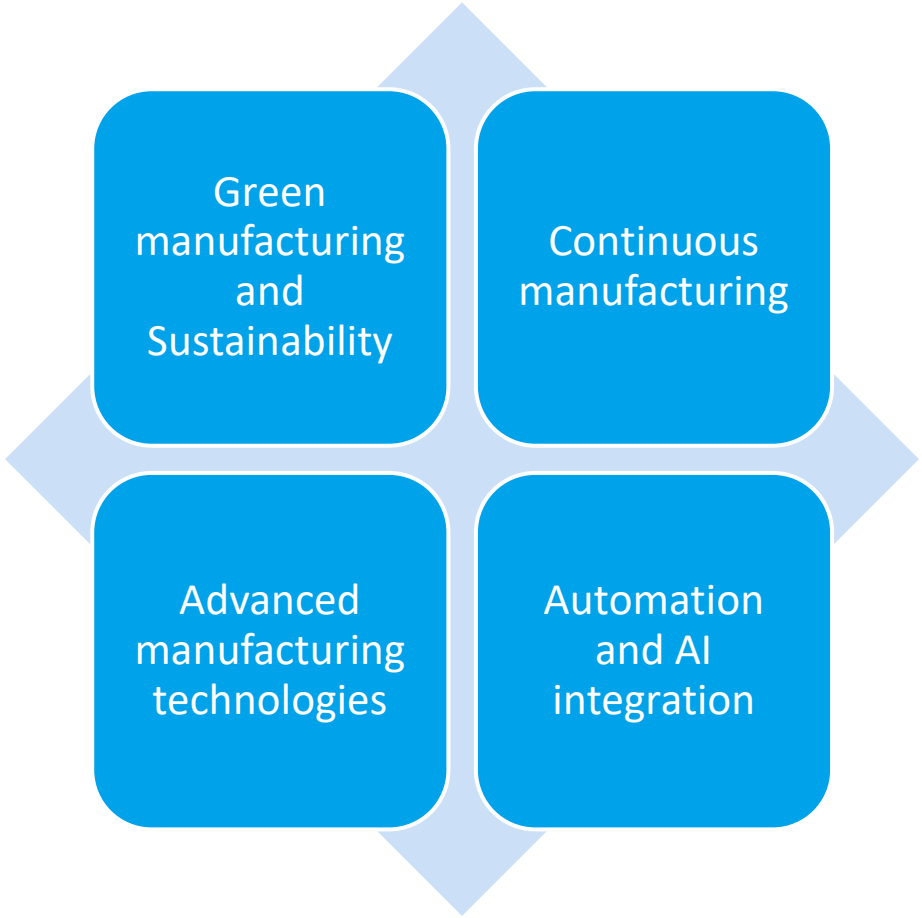
Trends API manufacturing



Challenges

- **Regulatory and Compliance changes/hurdles**
- High Investment
- Supply chain complexity

Need for International Collaboration and Reliance

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CEP is an attractive option

CEP = Certificate of Suitability to the monographs of the European Pharmacopoeia

The CEP procedure was established in 1994 and was initially only applicable to active substances

In 1999, the procedure was extended to include products with a risk of transmissible spongiform encephalopathy (TSE)

The procedure was further revised to allow for the control of herbal drugs and herbal drug preparations

CEP procedure

In scope

- Substances described in monographs in the Ph. Eur. (active substances, excipients, herbal drugs)

  → “Chemical” or “Herbal” CEP

- Products with risk of TSE (including intermediates, reagents, culture media..)

  → “TSE” CEP

Out of scope

- Substances not included in Ph. Eur. (except TSE CEP)
- Substances which do not comply with the Definition section of the monograph, if applicable
- Biologicals and products extracted from animal tissues
- Human tissues derivatives, blood derivatives, vaccines
- Finished products

Open to any manufacturer of pharmaceutical substances regardless of geographical origin

The CEP Procedure provides…

1. Centralised and harmonised assessment

Save time and resources!

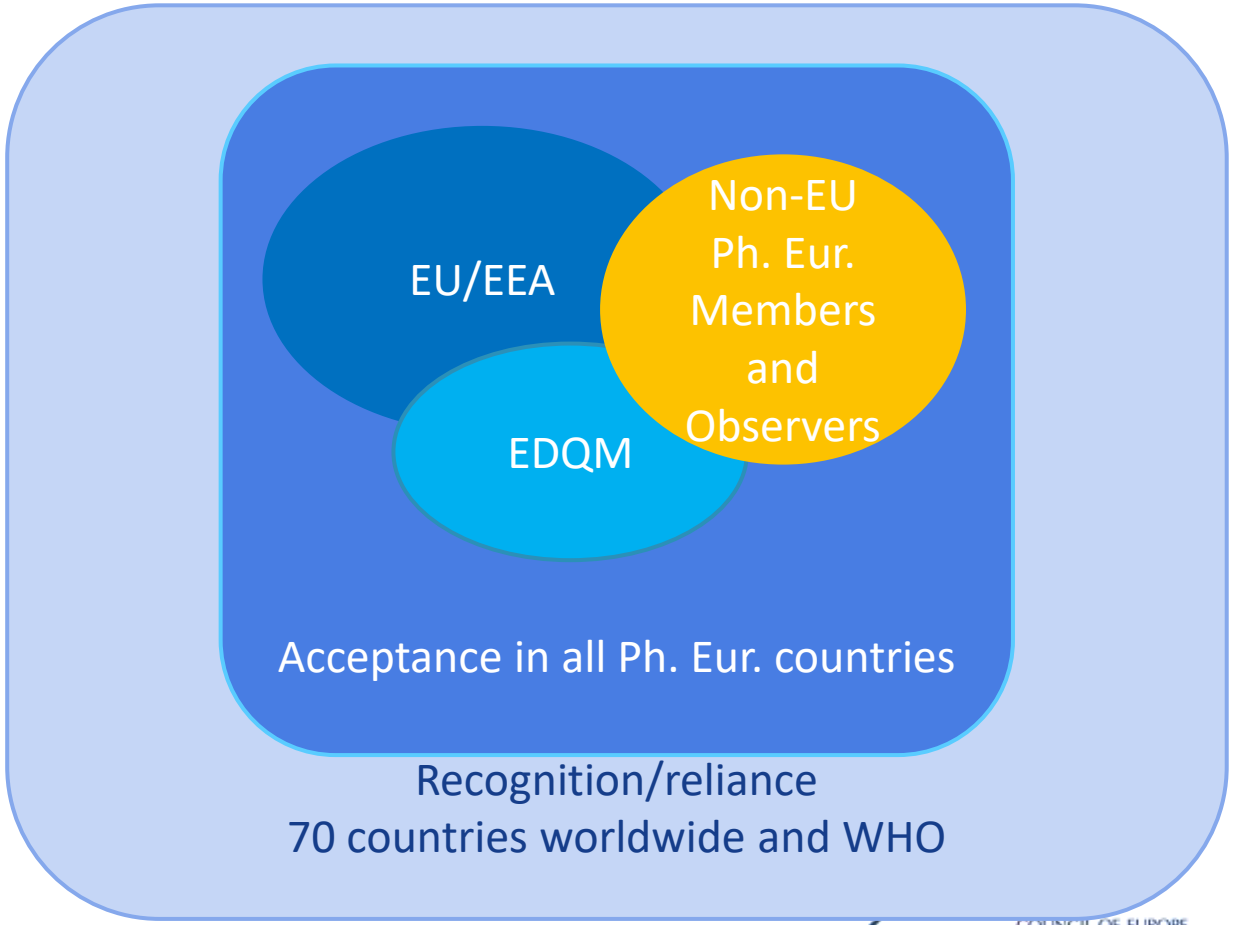
2. Application submitted directly to EDQM by the manufacturer of the pharmaceutical substance

3. Facilitates management of Marketing Authorisation Applications and their and variations

4. Information on the need to update Ph. Eur. Monographs

Acceptance of CEPs globally

- CEP are accepted by Ph.Eur. Convention Member States (39) + the EU and by other countries (e.g. Canada, Australia, Singapore, South Africa, Saudi Arabia, TFDA, Ghana, WHO, Brazil etc.)
- Exchange of information on acceptance of CEPs by **EDA** (Egypt), **NAFDAC** (Nigeria), **TITCK** (Turkyie)
- African Medicines Agency (**AMA**) setting up process for API assessment, acceptance of CEPs is part of the process



International Collaboration for CEPs

List of authorities and organisations which may have access to assessment and/or inspection reports

Organisation	Assessment reports	Inspection reports
Brazilian Health Regulatory Agency (ANVISA) Brazil	X	X
Health Products and Food Branch of the department of Health of Canada (HPFB) Canada	X	X
Health Sciences Authority (HSA) Singapore	X	X
Institute for Standardization and Control of Pharmaceuticals, Israeli Ministry of Health (ISCP) Israel	X	X
Ministry of Food and Drug Safety of the Republic of Korea (MFDS) South Korea	X	X
Ministry of Health, Labour and Welfare (MHLW) Japan		X
Pharmaceutical Inspection Co-operation Scheme (PIC'S) Switzerland		X
Saudi Food and Drug Administration (SFDA) Saudi Arabia	X	X
South Africa Health Products Regulatory Authority (SAHPRA) South Africa	X	X
Taiwan Food and Drug Administration of Ministry of Health and Welfare (TFDA) Chinese Taipei	X	X
Therapeutic Goods Administration (TGA) Australia	X	X
United States Food and drug Administration (USFDA) USA		X
World Health Organization (WHO) Switzerland	X	X

Bilateral confidentiality agreements/MoU with health authorities:

- to exchange confidential information concerning the quality of APIs and/or GMP status of manufacturing sites

With CEP 2.0: Extension of access to the secure **"Authorities database"** for regulatory authorities beyond Ph. Eur. accepting CEPs, under confidentiality agreements/MoU:

- Revised Holder's declarations in the CEP application form to allow confidential information sharing (June 2023)
- List of authorities which have access to the database displayed on the EDQM website (column "assessment reports" - Here)

Continued collaboration with other authorities

Reliance on others' API GMP inspections by EDQM

50% of GMP supervision for API manufacturing sites covered by CEPs is achieved by Reliance procedure

Source EEA inspections

- No API inspections on EEA territory
- Recognition of GMP Certificates for API manufacturing sites
- Actions taken based on Statement of GMP Non-Compliance for API sites involved in CEP scheme

Source other inspectorates

- Documentation based assessment
- Review of inspection reports from Trusted Authorities* (e.g. PIC/S)
- Result: accept outcome and include in re-inspection framework

* high degree of similarity between EU and the authority's inspection procedures and GMP standards (currently equivalent inspections can be considered in connection with an MRA, ACAA and PIC/S).

International Collaboration for the Ph. Eur.

- **Ph. Eur.: successful model of work-sharing and harmonisation between** currently **39 countries**, based on strong political will and legal commitment
- Ph. Eur., United States Pharmacopoeia, Japanese Pharmacopoeia and Indian Pharmacopoeia, with WHO as an observer, are partners in the **Pharmacopoeial Discussion Group** (PDG)
- **Prospective harmonisation:** joining forces on new monograph elaboration with other pharmacopoeias (individually with USP, JP and WHO)
- **Bilateral Agreements** / MoUs with pharmacopoeia authorities on collaboration and exchanges; involvement of observers in the elaboration of texts.
- **Global harmonisation (Good Pharmacopoeial Practices)**: EDQM key player in International Meeting of World Pharmacopoeias (IMWP)

Pharmacopoeial Discussion Group (PDG)

- Harmonisation of pharmacopoeial texts – focus is on general chapters and excipients monographs
  - 31 general texts and 48 excipients monographs harmonised
  - Work programme almost complete
  - Maintenance (revision) of harmonised texts
- PDG in charge of the maintenance of ICH Q4B guideline and its 16 annexes

➔via Q4B, goal is to achieve regulatory interchangeability among ICH authorities

➔Initiation of revision of ICH Q4B

- **Indian Pharmacopoeia Commission** (IPC) full PDG member since October 2023
- **Global expansion** initiative, for Pharmacopoeias willing to join:
  - **To fulfill entry criteria** to maintain optimal level of science and ensure PDG's progress
  - **To implement the complete PDG work programme**

Join us in paving the way for the future…

Contribute to the protection of public health by:

Making your comments count !

PHARMEUROPA ONLINE

Becoming part of a dynamic scientific community !

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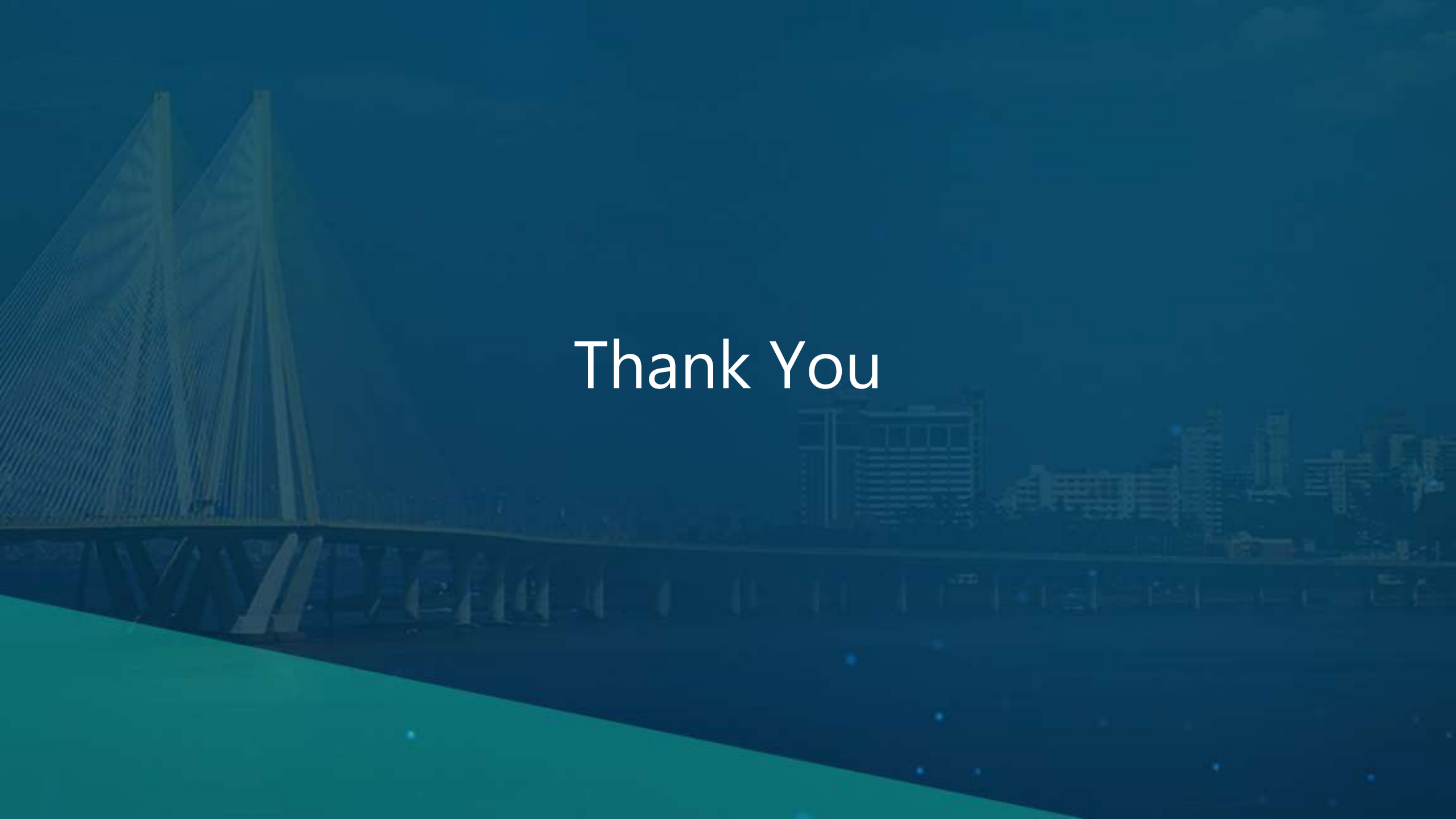
Thank You