



René van de Zande

President & CEO

René is responsible for all operations of the Emergo Group of companies worldwide. René founded Emergo Group in 1997 and as its President & CEO, he has a consistent record of delivering results in growth, revenue, operational performance, and profitability. Today, he spearheads the international expansion of Emergo Group's operations and service offerings, and provides guidance and support to Emergo Group teams on five continents.

Between 1990 and 1997, René worked in the capital of Europe, Brussels, Belgium, on European internal market issues and Trans-Atlantic business relations. He served as Senior Commercial Specialist at the U.S. Mission to the European Union. One of his responsibilities was monitoring and reporting on European legislation, particularly European Directives under the "New Approach" (CE Marking) including the Directives related to medical devices and in vitro diagnostics.

He participated in the Mutual Recognition Agreement negotiations between the US and the European Union. Mutual Recognition Agreements (MRAs) have the objective of promoting trade in goods between the European Union and third countries by facilitating market access. René was awarded a Certificate of Appreciation by U.S. Secretary of Commerce William M. Daley in June 1997 in recognition and appreciation of his outstanding effort and determination throughout the negotiation of the first Mutual Recognition Agreement with the European Union and his contribution in reaching an agreement that substantially enhances market access on both sides of the Atlantic and achieves the highest level of protection of safety and health.

René also participated in the Trans-Atlantic Business Dialogue (TABD) which was established to promote closer commercial ties between the U.S. and European Union. The TABD is an organization of chief executive officers from American and European businesses working together with government leaders to strengthen transatlantic economic relations with the objective to help establish a Barrier-Free Transatlantic Market. René's duties included providing support to the late US Secretary of Commerce Ron Brown who initiated the TABD, and US Ambassador of the US Mission to European Union, the Honorable Stuart Eizenstat, in preparation of and during the semi-annual TABD meetings.

Earlier René worked as Senior Issues Coordinator for the EU Committee of the American Chamber of Commerce in Brussels (now AmCham EU), which represents American multinationals' policy interests in the European Union. AmCham EU facilitates the resolution of EU - US issues that impact business and plays a role in creating better understanding of EU and US positions on business. His areas of responsibility were Trade & External Affairs, Financial Services & Company Law and Transport Policy.



René van de Zande, continued...

René also served as Managing Director of the European-American Industrial Council (EAIC), a group of senior executives from the largest multinational companies of US parentage based in Europe. EAIC's task was to help promote the commercial success of its members and help members build profitable businesses outside the US.

René has published numerous articles on medical device regulations and related issues. In addition, he is co-author of a series of publications on European product legislation for the U.S. Department of Commerce and the National Institute for Standards and Technology (NIST). He is also a frequent guest speaker on European regulatory affairs related to medical devices and in vitro diagnostics.

AREAS OF EXPERTISE:

- Global regulatory strategy for device compliance.
- CE Marking for Europe and European Authorized Representation.
- US FDA Device Compliance and US Agent representation.
- Australian TGA device compliance and Sponsor representation.
- Health Canada device licensing.
- Chinese SFDA device compliance and Legal Agent representation.
- Japan PAL regulatory requirements and D-MAH representation.
- Export and trade related issues.
- Trans-Atlantic business relations.

EDUCATION:

- Post-Graduate Degree from The Johns Hopkins University School for Advanced International Studies (SAIS).
- Masters Degree in Contemporary History from the University of Nijmegen, The Netherlands.