

National Interest Exception (NIE) Application How-To Guide

Where and How Do I Apply for an NIE?

The application for an NIE must be submitted to the U.S. consulate, regardless of whether a valid visa or ESTA approval is available or whether a new U.S. visa is being applied for.

The process of applying for a NIE may vary from country to country or from U.S. consulate to consulate. In addition, the application itself is constantly subject to change (e.g., contact email addresses change, etc.).

The NIE application is about supporting the urgency and importance of your trip to the United States. You must be able to demonstrate the planned activity must physically take place in the United States and cannot be rescheduled or conducted remotely.

Therefore, you generally need to prepare the following **NIE application documents**:

- Letter of justification and, if requested, further proof (e.g. Company Letter)
- Copy of passport
- Travel data
- ESTA approval/visa copy
- If necessary, further documents (depending on the U.S. consulate)

When Should I Apply for a NIE?

You should plan on approximately **three to six weeks*** to process your NIE application, although processing times vary depending on the U.S. consulate.

*Taking internal company policies and procedures into account, ISPE recommends that the NIE application is done by the beginning of September.

How long is my NIE valid?

NIEs are now valid for 12 months from the date of approval by the U.S. authorities and entitle the holder to multiple entries for the approved purpose of stay within this period.

What is the application fee?

For those who already hold a valid ESTA permit or U.S. visa, there is **no additional cost** for a NIE application. For a NIE application as part of a visa or ESTA application, the respective application fees for the visa or ESTA must be paid; however, there is no "NIE extra charge".

Summary:

NIE REQUEST WITH EXISTING VISA / ESTA	NIE REQUEST WHEN APPLYING FOR A VISA
1. Contact the U.S. consulate	
Request by e-mail to the responsible U.S. consulate	Regular visa appointment or emergency appointment (depending on visa category and consulate)
2. Submission of the NIE application documents	
Via e-mail	During the visa appointment with regular visa application documentation
3. Examination by U.S. consulate	
Processing time approx. 7-30 days	Examination on the day of the visa appointment if the conditions for visa and NIE are met
4. Granted NIE	
NIE approval by e-mail (waiver is also electronically registered)	Visa issuance (waiver is also electronically registered)
5. Refused NIE	
Entry currently not possible	Visa refusal (exclusion from VWP / ESTA, if applicable); entry currently not possible

When speakers for the 2021 ISPE Annual Meeting & Expo are from international companies, we recommend that the respective companies provide a strong business rationale:

- Why it is important that the employee speak/attend the 2021 ISPE Annual Meeting & Expo at the beginning of November?

Further details to consider:

- The application should be given on an existing Visa Waiver/ESTA**
 - If not, submit the requirements which correspond to your visa type and request

**Under a Visa Waiver/ESTA application the following should be submitted to your local US Embassy/Consulate:

- Attach scans of the ESTA approvals of all travellers and
- Attach scans of the passport data pages of all travellers and
- If you are not an EU citizen, attached a scan of my EU residency card
- Request is for business reasons (please explain and attach a letter from your company)

Guideline to the Content of the Application Letter

Details and Guidelines for Letter Content

- Details of event
 - Event name: 2021 ISPE Annual Meeting & Expo
 - Dates: 31 Oct – 3 Nov 2021
 - Adjust to what travel dates are being planned
- Apply as a Further Persons category, highlighting the Healthcare (including COVID-19 mitigation) focus – if necessary to mention
- (Insert your name) will be visiting and meeting with customers during their time in the USA
 - Elaborate on this aspect, with a strong business emphasis, if it is applicable

- Add any other business opportunities that the person can/will do whilst being in the USA.

Content for the Letter

*Note: Personalize the content below in red.

To Whom it May Concern:

With this e-mail, I apply for the National Interest Exception on the grounds of public health.

1. Company

- a. Company motivation and possible visits to the US sites
- b. Personal role in healthcare focus through company activities

2. International Society of Pharmaceutical Engineering (ISPE) (www.ispe.org)

ISPE is a not-for-profit association serving its Members through leading scientific, technical, and regulatory advancement across the entire pharmaceutical lifecycle. The 18,000+ Members of ISPE are building solutions in the development and manufacture of safe, effective pharmaceutical and biologic medicines, and medical delivery devices in more than 90 countries around the world. ISPE brings together pharmaceutical industry professionals and regulatory agencies, including FDA, WHO, PIC/S and other authorities, to work towards consistent and co-ordinated pharmaceutical outcomes.

On 31 Oct - 3 Nov 2021, ISPE will be hosting their in-person 2021 ISPE Annual Meeting & Expo in Boston, Massachusetts, USA. At this conference, the impact of COVID-19 on pharmaceutical production and the ways of insuring drug product supply will be discussed.

Content for Program Committee Attendee

As part of the program committee for the 2021 ISPE Annual Meeting & Expo, I will be leading and involved with conversations and activities with a specific focus on COVID-19 and vaccine manufacturing. In my role, it is vital to be present in-person to guide the pharmaceutical industry and to ensure the continued public health benefits that we are providing to patients worldwide.

In addition to my contributions as a program committee member, I will benefit as an attendee taking in the comprehensive education program featuring technical insights on the latest developments in supply chain, operations, facilities, equipment, information systems, product development, production systems, quality systems, regulatory guidance, and cutting-edge industry innovations. Sessions will be led by experts representing leading organizations in the pharmaceutical industry, including the FDA, AstraZeneca, Bayer, Biogen, Eli Lilly and Company, Sanofi, Takeda, Viatrix, and more.

In the ever-developing pharmaceutical industry, it is crucial that I participate in-person to contribute to the industry's greater good and proactively stay current with regulations, technologies, products, and manufacturing methods.

Content for Speaker Attendee

As a speaker at the 2021 ISPE Annual Meeting & Expo, I will be speaking on topics with a specific focus or impact on COVID-19 and vaccine manufacturing. In my role, it is vital to be present in-person to assist in sharing my knowledge with the pharmaceutical industry and to ensure the continued public health benefits that we are providing to patients worldwide.

In addition to my contributions as a program speaker, I will benefit as an attendee taking in the comprehensive education program featuring technical insights on the latest developments in supply chain, operations, facilities, equipment, information systems, product development, production systems, quality systems, regulatory guidance, and cutting-edge industry innovations. Sessions will be led by experts representing leading organizations in the pharmaceutical industry, including the FDA, AstraZeneca, Bayer, Biogen, Eli Lilly and Company, Sanofi, Takeda, Viatris, and more.

In the ever-developing pharmaceutical industry, it is crucial that I participate in-person to contribute to the industry's greater good and proactively stay current with regulations, technologies, products, and manufacturing methods.

Content for In-Person Attendee

As an attendee at the 2021 ISPE Annual Meeting & Expo, I will learn and collaborate with pharmaceutical industry professionals and regulators on topics that will focus on or impact on COVID-19 and vaccine manufacturing. In my role at my organization, it is vital to be present in-person to obtain this information first-hand and bring it back to my organization as we continue to work towards making viable medicines that impact patients worldwide.

The comprehensive education program will provide me technical insights on the latest developments in supply chain, operations, facilities, equipment, information systems, product development, production systems, quality systems, regulatory guidance, and cutting-edge industry innovations. Sessions will be led by experts representing leading organizations in the pharmaceutical industry, including the FDA, AstraZeneca, Bayer, Biogen, Eli Lilly and Company, Sanofi, Takeda, Viatris, and more.

In the ever-developing pharmaceutical industry, it is crucial that I participate in-person to proactively stay current with regulations, technologies, products, and manufacturing methods.

Sincerely,
(Insert Name)