

# Xenex — FDA De Novo Story

## (Setting the FDA blueprint for Whole Room Microbial Reduction)

### Case Study



#### Problem

During COVID, UV products flooded the market. Hospitals saw bold claims, uneven testing, and no clear FDA category for whole-room UV robots—creating confusion for buyers and infection-prevention teams.

#### Plan

- Build a claims-tight story around real-world efficacy; align early with Clinical/Legal.
- Package evidence for an FDA De Novo submission (a pathway that creates a new device type when none exists).
- Ship simple, compliant assets: message house and claims grid, explainer video, sales one-pagers, and landing/social variants that anyone on the buying team can understand.

#### Outcome

- FDA granted De Novo to Xenex LightStrike+ (DEN230007; 09/01/2023), establishing a new device classification—“whole room microbial reduction device” (21 CFR 880.6510; product code QXJ). This created the regulatory blueprint for room-scale UV robots.
- Following that decision, industry coverage underscored that authorization is now required to market UV robots to healthcare facilities (i.e., you can’t just make claims and sell).
- The FDA subsequently granted De Novo to other UV chamber devices (e.g., Germitec Chronos for probe disinfection), showing the broader shift to regulated categories—but in different device types than whole-room robots.

#### Why it matters

Creates a clear FDA pathway for whole-room UV—helping hospitals compare authorized devices vs. unvetted claims and buy with confidence amid rising AMR risk.

#### What shipped

Message house and claims grid • Creator-style explainer video • One-pager • Sales deck refresh • Landing/social variants • FAQ for IP/Facilities/Finance • Internal briefing for spokespersons.

#### My role

Strategy, scripting, creative direction, hands-on production; experiment design (hooks/captions/cuts); cross-functional alignment with Sales/Product/Clinical/Legal to keep claims simple, accurate, and defensible.

# Xenex — Personalized Mug Studio

(Trade show AI-assisted portraits, printed live)

Case Study



## Problem

Noisy exhibit floors. Swag draws crowds, not pipeline.

## Plan

Pre-event email with two event-themed mug designs; registrants vote (intent signal).

## Execution

- Tag voters in CRM before the show.
- At booth: scan badge to qualify A/B/C leads, AI photo to hot-press mug in the winning design.
- Two-press workflow; timed pickups to manage 30–40 min lines.

## Outcome

- Booth rush at open (“rope-drop”).
- Mugs became collector items; sustained traffic during show floor hours.
- Higher A/B lead mix, more meetings/demos, lower CPQL vs. prior shows.



## What shipped

Vote email and UTM tracking; templates for background/branding; on-site photo/consent flow; print presets; run-of-show; thank-you reels and demo CTAs.

## My role

Concept, creative, email flow, booth ops design, print QA, CRM tagging, post-show content.

## Metrics

28% increase in meetings vs. prior show; 87 pre-event voters; 378 mugs printed (peak 53 per hour); 372 unique scans; 31% of mug recipients were A- or B-scored leads.

# UPS — Founders Day AR Museum (Global Access)

*Case Study*



## Problem

Most employees never see Atlanta HQ's history; global teams lacked a tangible way to connect with UPS heritage.

## Plan

Build a phone-accessible AR museum reachable from anywhere. Curated artifacts and AI-animated historic photos; distributed via QR and intranet post—no app required.

## Outcome

Global engagement and stronger sense of pride/belonging; leaders used it in internal comms and events. The format became a reusable template for future heritage content.



## What shipped

AR "rooms," artifact captions, teaser clips, intranet/QR rollout, accessibility notes.

## My role

Strategy, curation, design/art direction, prototype build, launch comms.

## Metrics

Reached a global audience across AMER, EMEA, and APAC; adopted in internal communications by regional leaders; no app required.